

EPA Registration No.  
39967-137  
Vol. 2



ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF PESTICIDE PROGRAMS (TS-767)  
WASHINGTON, DC 20460

# NOTICE OF SUPPLEMENTAL REGISTRATION OF DISTRIBUTOR

(Please read instructions before completing)

EPA REGISTRATION NO. OF PRODUCT

DISTRIBUTOR COMPANY NUMBER

0 62432-18

9 270

NAME AND ADDRESS OF BASIC REGISTRANT (print or type; include ZIP code)

ANTEC INTERNATIONAL, LTD.  
Windham Road,  
Chilton Industrial Estate  
Sudbury, Suffolk CO10 6XD  
England

NAME OF REGISTERED PRODUCT (basic product name accepted by EPA)

VIRKON S Broad Spectrum Disinfectant

DISTRIBUTOR PRODUCT NAME

VIRKON S Broad Spectrum Disinfectant

NAME AND ADDRESS OF DISTRIBUTOR (print or type; include ZIP code)

Livestock Products Division  
Farnam Companies, Inc.  
P.O. Box 34820  
Phoenix, AZ 85014

## DISTRIBUTOR

We intend to market under the Distributor Product Name and Number specified above, subject to the conditions specified on this form.

SIGNATURE AND TITLE OF DISTRIBUTOR

X Douglas H. Ross, Regulatory Specialist

DATE

X 9 FEB 98

## REGISTRANT

It is requested that the Registration Record of this jacket include the Distributor Product specified above, subject to the conditions specified on this form.

SIGNATURE AND TITLE OF REGISTRANT

Alan R. Wagner D.V.M., M.S.  
Alan R. Wagner, D.V.M., M.S., Agent for

DATE

10 October 1997

## INSTRUCTIONS

After a registrant has obtained final registration for the basic product, the registrant may then supplementally register and distribute his/her product. One form must be submitted for each distributor brand and must be signed by the distributor involved. The form must state the basic registration number and the distributor company number.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationary, to the Registration Division to have a number assigned prior to submitting a Distributor Notification to the Agency.

Notification forms must be submitted by the basic registrant. They must have the concurrence and signature of both the registrant and the distributor.

When submitting several forms for the same basic product, submitting them together will facilitate processing.

**NOTE: DO NOT** submit distributor product labels.

## CONDITIONS

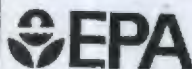
1. The distributor product must have the same composition as the basic registered product.
2. The distributor brand product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so no other changes are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic registered product, followed by a hyphen and the distributor's company number.
6. Distributor products must bear the name and address of the distributor, qualified by such terms as "distributed by" or "sold by" to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor brand products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

RECEIVED BY EPA REGISTRATION DIVISION ON THE DATE STAMPED BELOW



2-18-98



ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF PESTICIDE PROGRAMS (TS-767)  
WASHINGTON, DC 20460  
**NOTICE OF SUPPLEMENTAL REGISTRATION OF DISTRIBUTOR**

(Please read instructions before completing)

EPA REGISTRATION NO. OF PRODUCT

DISTRIBUTOR COMPANY NUMBER

0 62432-18

7 43591

NAME AND ADDRESS OF BASIC REGISTRANT (print or type; include ZIP code)

ANTEC INTERNATIONAL, LTD.  
Windham Road,  
Chilton Industrial Estate  
Sudbury, Suffolk CO10 6XD  
England

NAME OF REGISTERED PRODUCT (basic product name accepted by EPA)

VIRKON S Broad Spectrum Disinfectant

DISTRIBUTOR PRODUCT NAME

Trifectant Broad Spectrum Disinfectant

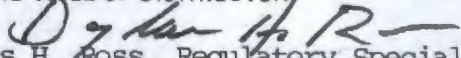
NAME AND ADDRESS OF DISTRIBUTOR (print or type; include ZIP code)

Veterinary Products Laboratories  
PO BOX 34820  
Phoenix, AZ 85067-4820

## DISTRIBUTOR

We intend to market under the Distributor Product Name and Number specified above, subject to the conditions specified on this form.

SIGNATURE AND TITLE OF DISTRIBUTOR

X   
Douglas H. Ross, Regulatory Specialist

DATE

X 9 FEB 98

## REGISTRANT

It is requested that the Registration Record of this jacket include the Distributor Product specified above, subject to the conditions specified on this form.

SIGNATURE AND TITLE OF REGISTRANT

Alan R. Wagner D.V.M., M.S.  
Alan R. Wagner, D.V.M., M.S., Agent for

DATE

10 October 1997

## INSTRUCTIONS

After a registrant has obtained final registration for the basic product, the registrant may then supplementally register and distribute his/her product. One form must be submitted for each distributor brand and must be signed by the distributor involved. The form must state the basic registration number and the distributor company number.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationary, to the Registration Division to have a number assigned prior to submitting a Distributor Notification to the Agency.

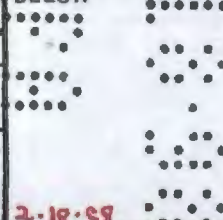
Notification forms must be submitted by the basic registrant. They must have the concurrence and signature of both the registrant and the distributor.

When submitting several forms for the same basic product, submitting them together will facilitate processing.

NOTE: DO NOT submit distributor product labels.

## CONDITIONS

1. The distributor product must have the same composition as the basic registered product.
2. The distributor brand product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so no other changes are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic registered product, followed by a hyphen and the distributor's company number.
6. Distributor products must bear the name and address of the distributor qualified by such terms as "packed for . . ." "distributed by . . ."; or "sold by . . ." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor brand products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

RECEIVED BY EPA REGISTRATION  
DIVISION ON THE DATE STAMPED  
BELOW

2-18-98





United States Environmental Protection Agency  
Office of Pesticide Programs (H7505C)  
401 M Street SW  
Washington, DC 20460

# Notice of Supplemental Distribution of a Registered Pesticide Product

## Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationary, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product

0 62432-1 8

Distributor Company Number

2 12281

**Note: Do not submit distributor product labels**

Name of Registered Product (basic product name accepted by EPA)

VirKon S

Distributor Product Name

VirKon S

Name and Address of Distributor (Type; include ZIP code)

Durvet, Inc.  
P.O. Box 279  
24010 Highway 40 Eastbound  
Blue Springs, MO 64015

## Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by..."; or sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

## Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

*Robert E. Homann*

President

Date  
12/28/93

## Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

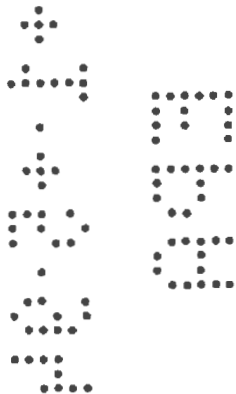
Signature and Title of Registrant

*U.S. Agency for Pesticide Control*

Date  
12/31/93

## Paperwork Reduction Act Notice

The annual respondent burden for the Notice of Supplemental Distribution of a Registered Pesticide Product is estimated to average 15 minutes per response, including time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information. Send comments regarding this burden, to chief, Information Policy Branch, PM 223, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460; and to Paperwork Reduction Project (OMB No. 2070-0044), Office of Management and Budget, Washington, DC 20503, Marked "Attention Desk Officer for EPA."





**TASK ASSIGNMENT FORM**  
**Antimicrobial Division/Regulatory Management Branch II**

<b>A</b>	Completed by Product Manager						
PRODUCT REVIEWER <b>Sherrie Gray</b>					RMB <u>II</u> TEAM <u>34</u>		
Description of Action:					EPA File Symbol/Reg No. <b>71654-6</b>		
Decision No. <u>359708</u>		Submission No. <u>762928</u>		Fee for Service Action Code:			
FQPA Action Code: <b>332</b>		Non-FQPA Action Code:		PRIA FEE AMOUNT: \$			
		MONTH	DAY	YEAR			
APPLICATION DATE		JULY	29	2005			
EPA PIN DATE		AUGUST	01	2005			
REVIEWER ASSIGNED DATE		AUGUST	11	2005			
DATE DUE FROM SCIENCE							
DATE DUE TO PM		AUGUST	21	2005			
DATE DUE OUT OF AGENCY							
Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure
<b>COMMENTS:</b> <i>NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM</i>							
<b>ATTACHMENTS:</b> <input type="checkbox"/> LABELING <input type="checkbox"/> CSF(S) <input type="checkbox"/> DATA <input type="checkbox"/> OTHERS							
<b>B</b>	For Arctic Slope Contract Only						
Contractor: Arctic Slope				Contract No.: 0332		ARCTIC SLOPE/MANAGER	
Draft Task: Signature _____ (Est. hrs)				Final Task: Signature <u><i>SG</i></u> <u>15</u> (Total hrs)			
<b>C</b>	Reviewer's Comments:						
DATE FEE PAID:				RESPONSE CODE: <u>17</u> RESPONSE DATE: <u>8/25/05</u>			





DuPont Chemical Solutions Enterprise

July 29, 2005

Document Processing Desk  
Antimicrobials Division (7510C)  
US Environmental Protection Agency  
Office of Pesticide Programs  
Mr. Adam Heyward (PM34)  
Room 266A, Crystal Mall #2  
1801 S. Bell Street  
Arlington, VA 22202-4501

**Reference: Virkon ® S ( EPA Registration No. 71654-6)**

Dear Mr. Heyward,

Please find the attached application form 8570-1 for notification of the alternate brand name:

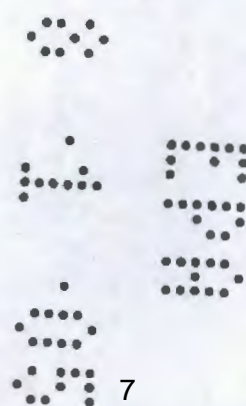
Virkon ® Aquatic Disinfectant and Virucide

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I understand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

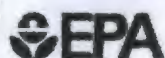
Should you have any questions, feel free to call.

Sincerely,

Thomas C. McEntee  
Product Registration Manager  
Thomas.C.McEntee@usa.dupont.com  
DuPont Chemical Solutions Enterprise  
Barley Mill Plaza, P. O. Box 80023  
4417 Lancaster Pike  
Wilmington, DE 19805







United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 71654-6	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Virkon (R) S	PMS 34	
5. Name and Address of Applicant (Include ZIP Code) E.I. du pont de Nemours & Company Dupont Chemical Solutions Enterprise, P. O. Box 80023 Wilmington, DE 19880-0023  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of Alternate Brand Name per PR Notice 98-10 Virkon (R) Aquatic Disinfectant and Virucide

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulation at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I understand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
Certification must be submitted If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 10 lb., 1lb., 9 oz.		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Thomas C. McEntee		Title Product Registration Manager	
		Telephone No. (Include Area Code)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			8. Date Application Received (Stamped)  
2. Signature 		3. Title Product Registration Manager	
4. Typed Name Thomas C. McEntee		5. Date July 29, 2005	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

August 25, 2005

Thomas C. McEntee  
Product Registration Manager  
E.I. du Pont de Nemours and Company  
DuPont Chemical Solutions Enterprise  
P.O. Box 80023  
Wilmington, DE 19880-0023

Subject: Virkon® S  
EPA Registration Number 71654-6  
Application Date: July 29, 2005  
EPA Received Date: August 1, 2005

Dear Mr. McEntee:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

**Proposed Notification**

Alternate Brand Name "Virkon® Aquatic Disinfectant and Virucide"

**General Comments**

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,

Adam Heyward  
Product Manager 34  
Regulatory Management Branch II  
Antimicrobials Division (7510 C)

		CONCURRENCES			
SYMBOL	75104				
SURNAME	Heyward				
DATE	8-25-05				



DuPont Chemical Solutions Enterprise

June 17, 2005

Mr. Adam Heyward  
Antimicrobials Division (7510C)  
US Environmental Protection Agency  
Office of Pesticide Programs  
Ariel Rios Building  
1200 Pennsylvania Avenue NW  
Washington, DC 20460

Subject: Virkon ® S  
EPA Registration No. 71654-6  
Your letter of October 21, 2004

This letter is to confirm that the studies required to address the deficiencies referred to in your October 21, 2005 letter are underway. With the exception of full one-year storage stability, completed studies are expected to be submitted by August 1, 2005.

Should you have any questions, feel free to call.

Sincerely,

A handwritten signature in dark ink, appearing to read "Thomas C. McEntee", written in a cursive style.

Thomas C. McEntee  
Product Registration Manager  
(302) 992-3771



71654-6

**TASK ASSIGNMENT FORM**  
**Antimicrobial Division/Regulatory Management Branch II**

<b>A</b>	Completed by Product Manager					
PRODUCT REVIEWER: <u>Adam Heyward</u>					RMB <u>II</u> TEAM <u>34</u>	
Description of Action:					EPA File Symbol/Reg No.: <u>62432-1</u>	
Decision No. <u>342206</u>		Submission No. <u>758567</u>		Fee for Service Action Code: _____		
FQPA Action Code: _____		Non-FQPA Action Code: <u>400</u>		Fee for Service Fee: \$ _____		
		MONTH	DAY	YEAR		
APPLICATION DATE		<u>11</u>	<u>07</u>	<u>2003</u>		
EPA PIN DATE		<u>11</u>	<u>10</u>	<u>2003</u>		
REVIEWER ASSIGNED DATE		<u>04</u>	<u>19</u>	<u>2004</u>		
DATE DUE TO PM				<u>2004</u>		
DATE DUE OUT OF AGENCY				<u>2004</u>		
Type of Data:	Product Chemistry <input type="checkbox"/>	Acute Toxicology <input type="checkbox"/>	Efficacy <input type="checkbox"/>	Environmental Fate <input type="checkbox"/>	Ecological Effects <input checked="" type="checkbox"/>	Chronic Toxicology <input checked="" type="checkbox"/> Exposure <input type="checkbox"/>
COMMENTS: <u>NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM.</u>						
DP Barcode No(s): _____						
<b>B</b>	For Arctic Slope Contract Only					
Contractor: Arctic Slope			Contract No.: 0332		ARCTIC SLOPE/MANAGER	
Draft Task: Signature _____ (Est. hrs)			Final Task: Signature _____ (Total hrs)			
<b>C</b>	Reviewer's Comments:					
Response Code: <u>38</u> Response Date: <u>2-8-05</u>						





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**February 8, 2005**

T. Jeffrey Jones  
Delta Analytical Corporation  
The agent for  
**E. I. DUPONT De Nemours and Company**  
7910 Woodmont Avenue, Suite 1000  
Bethesda, Maryland 20814

Subject: Potassium Hydrogen Peroxymonosulfate Ecotoxicity Studies  
Submitted in Accordance with FIFRA Section 6(a)(2)  
**VIRKON S**  
EPA Registration No. 71654-6  
**VIRKON**  
EPA Registration No. 71654-7  
Applications Date: November 7, 2003  
Final Receipt Date: November 10, 2003

Dear Mr. Jones:

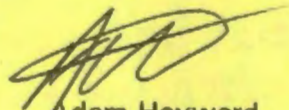
The Agency has completed its reviewed of the Ecotoxicity studies submitted in accordance with FIFRA Section 6(a)(2) on Potassium Hydrogen Peroxymonosulfate Sulfate. Several aquatic animal toxicity tests were submitted for the active ingredient Potassium Hydrogen Peroxymonosulfate Sulfate. A total of three studies was reviewed. The status and results of the submitted Potassium Hydrogen Peroxymonosulfate Sulfate Ecological Effects Studies are listed in the table below:

Study	Species	MRID	Status	Results
Fresh Water Fish Acute	Trout	461190-01	<i>Core</i>	LC <sub>50</sub> = 53 mg/L, NOEC = 27 mg/L
Freshwater Invertebrate Acute	Daphnid	461190-02	<i>Core</i>	EC <sub>50</sub> = 3.5 mg/L, NOEC = 2.5 mg/L
Green Alga	<i>Selenastrum</i>	461190-03	<i>Core</i>	EbC <sub>50</sub> = 1.0 mg/L, NOEC = 0.5 mg/L

For detailed information and considerations, refer to the enclosed EPA/AD Risk Assessment and Science Support Branch Ecotoxicity Data Evaluation Record (DER) for Potassium Hydrogen Peroxymonosulfate Sulfate dated June 15, 2004.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422.

Sincerely,



Adam Heyward  
Product Manager 34  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

Enclosure: (Potassium Hydrogen Peroxymonosulfate Sulfate DER)





November 7, 2003

Document Processing Desk - 6(a)(2)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501

*PC Code*  
*013905*  
*Sodium*  
*Potassium*

SUBJECT: Information Submitted in Accordance with FIFRA Section 6(a)(2)  
Report of studies and Incidents with potassium peroxymonosulfate (CAS  
#70693-62-8); Active ingredient in EPA Reg #s 62432-1 and 62432-2

*063604*

To Whom It May Concern:

We have recently become aware of several studies conducted on potassium peroxymonosulfate and related materials which we are submitting under FIFRA 6(a)(2).

On October 8, 2003, ANTEC INTERNATIONAL LTD. became a wholly owned subsidiary of DU PONT (U.K.) LTD, a U.K. corporation. Antec International continues to be the US registrant for two disinfectant products that contain the active ingredient potassium peroxymonosulfate (CAS #70693-62-8).

EI DuPont de Nemours & Company, a U.S. corporation, has been a manufacturer of potassium peroxymonosulfate for over 40 years for a variety of industrial (non-pesticidal) uses, and previously for pesticidal uses which were voluntarily canceled. DuPont does not hold any FIFRA registrations for this material. Over the course of the product's development and history, a number of toxicology and environmental studies have been conducted by DuPont to support the product stewardship of this product as well as to meet a variety of global regulatory requirements. DuPont has informed us that they previously met their TSCA 8e reporting obligations with respect to these studies.

Subsequent to DuPont's acquisition of Antec, DuPont forwarded to Antec its file of unpublished studies on this compound. Antec has reviewed these studies and is submitting several of them to the Agency pursuant to EPA's FIFRA Section 6(a)(2) regulations.



Three copies of each of the following (12) studies summarized below are being submitted herein:

- **Volume 1 of 12**

Oxone ® Monopersulfate Compound: Acute Toxicity to Fish (DuPont Report #5755):

MRID# **46119001**

This ecological study appears to be reportable in accordance with 40 CFR 159.165(b), as it reports results of a previously untested species; in this study the 96 hour LC50 in rainbow trout was determined to be 53 mg/L

- **Volume 2 of 12**

Oxone ® Monopersulfate Compound: Acute Toxicity to *Daphnia magna* (DuPont Report #5756):

MRID# **46119002**

This ecological study appears to be reportable in accordance with 40 CFR 159.165(b), as it reports results of a previously untested species; in this study the 48 hour EC50 in *Daphnia* was determined to be 3.5 mg/L

- **Volume 3 of 12**

Oxone ® Monopersulfate Compound: Algal Growth Inhibition Assay (DuPont Report #5757):

MRID# **46119003**

This study appears to be reportable in accordance with 40 CFR 159.165(b), as it reports results of a previously untested species; in this study the 96 hour EC50 in the green alga *Selenastrum* was determined to be 1 mg/L.

- **Volume 4 of 12**

Oxone ® Monopersulfate Compound: Acute Oral Toxicity to the Rat (Acute Toxic Class Method) ; (DuPont Report #5763)

MRID# **46119004**

This study is being reported in accordance with 40 CFR 159.165(a). Rats were exposed to single oral gavage doses of either 200 or 2000 mg/kg test material. There were no deaths or clinical signs in rats exposed to the low dose. All 3 rats treated with 2000 mg/kg died within the first 24 hours of dosing. Although these results are consistent with the established oral LD50 in rats of 1100 mg/kg, we are submitting this study under FIFRA 6a2 as we cannot confirm whether or not the clinical signs reported at this lethal dose is identical to those reported in studies previously known to the Agency.

- **Volume 5 of 12**

Elchem 1384 (High Strength Bleach): Acute Oral Toxicity in Rats (DuPont Project ID: MR 391)

MRID# **46119005**

This study is being reported in accordance with 40 CFR 159.165(a). Rats were exposed to single oral doses of test material ranging from 670 – 5000 mg/kg. This 1957 study is being submitted as it reports clinical observations within the first hour after dosing, and thus may include clinical signs following a shorter exposure period than reported in previously submitted acute toxicity studies.

- **Volume 6 of 12**

Inhalation Median Lethal Concentration (LC<sub>50</sub>) Study with H-20981 in Rats (DuPont Report # HLR 284-95)

MRID# **46119006**

This study is being reported in accordance with 40 CFR 159.165(a). Rats were exposed (nose only) to concentrations of 2.5, 3.1 or 4.8 mg/L particulate Virkon S for 4 hours. The LC50 was determined to be 3.7 mg/L. Following exposure, the surviving rats exhibited body weight losses, and clinical signs including nasal and ocular discharges, hunched posture, lethargy, weakness, diarrhea, enophthalmus, irregular respiration, lung noise.

- **Volume 7 of 12**

Oxone ® Monopersulfate Compound: Toxicity Study by Oral Administration to CD Rats for 13 Weeks (DuPont Report # 5765)

MRID# **46119007**

The significant results from this study were previously provided to EPA by DuPont pursuant to TSCA § 8(e). We are submitting the complete study report for EPA's files.

- **Volume 8 of 12**

Evaluation of Primary Irritation Potential in Humans Exposed to Sodium Peroxydisulfate, Ammonium Peroxydisulfate, and Impact® (DuPont Report #HLO-754-93)

MRID# **46119008**

This study is being reported in accordance with 40 CFR 159.170. Although the results are not inconsistent with those results seen in dermal irritation studies in animals, these studies are being submitted to the Agency as they are studies reporting observations of potential effects following exposures to humans.



- **Volume 9 of 12**

Evaluation of Primary Irritation Potential in Humans Exposed to Ammonium Persulfate, Sodium Persulfate, Impact® and Pool Water (DuPont Report #HLO-753-93)

MRID# **46119009**

This study is being reported in accordance with 40 CFR 159.170. Although the results are not inconsistent with those results seen in dermal irritation studies in animals, these studies are being submitted to the Agency as they are studies reporting observations of potential effects following exposure to humans.

- **Volume 10 of 12**

100 Person Human Patch Test with Ammonium Persulfate, Sodium Persulfate, and Impact® (DuPont Report #HLO-400-92)

MRID# **46119010**

This study is being reported in accordance with 40 CFR 159.170. The purpose of this study was to determine whether or not exposure to the test materials under the conditions of a patch test would adversely affect the skin, either as an irritant or sensitizer, or both. Based on the effects observed with the materials placed repeatedly on the skin during the primary application and challenge phases, the 3 test materials demonstrated irritation and skin sensitization propensities under the test conditions. However, since the 3 materials were tested concurrently, it is unclear from these results whether the hypersensitivity induced by each of these materials was influenced by the other test substances.

- **Volume 11 of 12**

Evaluation of Dermal Sensitization Potential of Impact® in Humans (DuPont Report #HLO-498-92)

MRID# **46119011**

This study is being reported in accordance with 40 CFR 159.170. The significant results from this study were previously provided to EPA by DuPont pursuant to TSCA § 8(e). We are submitting the complete study report for EPA's files

- **Volume 12 of 12**

Acute Oral Toxicity Study with H-21263 in Male and Female Rats (DuPont Report #HLR 590-95)

MRID# **46119012**

This study is being reported in accordance with 40 CFR 159.165(a). Rats were exposed to single oral doses by intragastric intubation at 2300, 3400, and 5000 mg/kg body weight. The combined LD50 for male and female rats was calculated to be 4123 mg/kg with a confidence limit of 2477 to 3834 mg/kg of body weight. Although these results are



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

**MEMORANDUM**

Subject: 6 (a)(2) Screening for Sodium chloride (1.5%), Potassium peroxymonosulfate (20.4%)

EPA Reg:62432-1

Sodium chloride (1.5%), Potassium peroxymonosulfate (20.4%)

DP Barcodes: D299148

PC code: 013905, 063604

From: Nader Elkassabany, Team Leader *Nader Elkassabany 3/31/04*  
Risk Assessment and Science Support Branch (RASSB), Antimicrobials Division (AD)[7510C]

To: Adam Heyward, PM 34  
Sharon Carlisle, PM Team Reviewer  
Regulatory Management Branch  
Antimicrobials Division [7510C]

Thru: Norm Cook, Chief, RASSB/AD [7510C]

Applicant: ANTEC INTERNATIONAL LTD

**ACTION REQUESTED:** Review the attached submission for 6 (a)(2) screening, MRID 46119001, 46119002, 46119003, 46119004, 46119005, 46119006, 46119007, 46119008, 46119009, 461190010, 461190011, and 461190012.

**CONCLUSIONS:** The submission of the studies above does not qualify as a 6(a)2 submission and an expedited review is not necessary.





December 11, 2003

Document Processing Desk – 6(a)(2)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501

SUBJECT: CORRECTION to submission dated 6 November 2003  
Information Submitted in Accordance with FIFRA Section 6(a)(2)  
Report of Studies and Incidents with potassium peroxydmonosulfate (CAS  
#70693-62-8); Active ingredient in EPA Reg #s 62432-1 and 62432-2

To Whom It May Concern:

On November 7, 2003 I submitted a FIFRA Section 6(a)(2) notification applying to an active ingredient in Antec International Ltd.'s pesticide products, Virkon S and Virkon (EPA Reg. No.'s 62432-1 and 62432-2). Subsequently, I was contacted by Kathleen O'Malley who asked that I submit corrected pages to cure PR Notice 86-5 deficiencies that had been identified during the screening process. In addition, one of my colleagues noticed that I had dated the Data Confidentiality and GLP signature pages incorrectly. The date of my signatures on these pages was recorded as "6 OCT 2003" rather than 6 NOV 2003." Since I executed these documents on November 6, 2003, the day before they were submitted, I am attaching the title page and corrected pages for the twelve studies previously submitted.

I am sorry if these errors cause any inconvenience.

Sincerely,

A handwritten signature in black ink, appearing to read "T. Jones", is written over the word "Sincerely,".

T. Jeffrey Jones, Agent  
Antec International, Ltd.

cc: Mark Squire, Chief Chemist  
Antec International, Ltd.

7910 Woodmont Avenue Suite 1000 Bethesda, Maryland 20814  
(301) 652-5495 FAX (301) 652-5408



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

January 11, 2005

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

**MEMORANDUM:**

**SUBJECT:** Screen Adverse Data [FIFRA 6(a)(2)] submission for Virkon® S, EPA  
Reg. No. 71654-6 Containing Sodium chloride and Potassium  
peroxymonosulfate

**TO:** Adam Heyward, Product Manager, Team 34  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

**FROM:** Srinivas Gowda, Microbiologist/Chemist *Srinivas Gowda 1/11/05*  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510C)

**THRU:** Siroos Mostaghimi, Acting Team Leader, Team One *Siroos - Mosty*  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510C)

Norm Cook, Chief *Norm Cook*  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510C)

**DP Barcode:** D311802  
**Decision #:** 352289  
**Case Type:** Adverse Data 6(a)(2)  
**PC Codes:** 013905 & 063604  
**Chemical Names:**  
Sodium Chloride  
Potassium peroxymonosulfate

**EPA Reg. No.:** 71654-6  
**MRID No.:** 463493-01  
**Data Submitter:** DuPont Chemical  
**CAS#:** 7647-14-5 (Sodium Chloride)  
10058-23-8 (Potassium peroxymonosulfate)



## **INTRODUCTION:**

DuPont Chemical Solutions Enterprises, has submitted Adverse Data (Chronic Trout Study) in Accordance with FIFRA Section 6(a)(2) for Virkon® S (EPA Reg. No. 71654-6). 6(a)(2) Coordinator, Sharon Carlisle, requests RASSB to screen and make a determination whether the package needs to be expedited quickly as a 6(a)(2) submission. The submitted adverse data (Chronic Trout Study) has undergone review by Srinivas Gowda of Antimicrobials Division's Risk Assessment and Science Support Branch.

## **RECOMMENDATIONS:**

The submitted Adverse Data (Chronic Trout Study) under the MRID No. 463493-01 does not qualify as a 6(a)(2) submission. Risk Assessment and Science Support Branch recommends that the Chronic Trout Study for Virkon® S, EPA Reg. No. 71654-6, must be rerouted to RASSB for review under a miscellaneous (400) PRAT Code and revised due date.

**DATA PACKAGE BEAN SHEET**

Date: 14-Jan-2005

Page 1 of 1

**\*\*\* Registration Information \*\*\***

Registration: 71654-6 - VIRKON S

Company: 71654 - E.I. DUPONT DE NEMOURS AND COMPANY

Risk Manager: RM 34 - Adam Heyward - (703) 308-6422 Room# CM-2 308B

Risk Manager Reviewer: Sharon Carlisle SCARLISL

Sent Date: 29-Dec-2004

Calculated Due Date: 08-Nov-2004

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (405) ADVERSE DATA (6A2):

Ingredients: 013905, Sodium chloride(1.5%)

063604, Potassium peroxyxymonosulfate(20.4%)

**\*\*\* Data Package Information \*\*\***Expedite: ☐ Yes ☒ No

Date Sent: 29-Dec-2004

Due Back:

DP Ingredient: 013905, Sodium chloride

063604, Potassium peroxyxymonosulfate

DP Title:

CSF Included: ☐ Yes ☒ NoLabel Included: ☐ Yes ☒ No

Parent DP #:

**Assigned To****Date In****Date Out**

Organization: AD / RASSB

29-Dec-2004

14-Jan-2005

Administrative Due Date: 23-Jan-2005

Team Name: RASSB1.

29-Dec-2004

14-Jan-2005

Negotiated Due Date:

Reviewer Name: Gowda, Srinivas

29-Dec-2004

14-Jan-2005

Projected Completion Date:

Contractor Name:

**\*\*\* Studies Sent for Review \*\*\***

No Studies

**\*\*\* Additional Data Package for this Decision \*\*\***

No Additional Data Packages

**\*\*\* Data Package Instructions \*\*\***

RASSB: The attached data MRID# 46349301 is being submitted for a 6(a)(2) screening





## DuPont Chemical Solutions Enterprise

## DELIVERED BY COURIER

August 24, 2004

Document Processing Desk - 6(a)(2)  
Office of Pesticide Programs(7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1801 S. Bell St.  
Arlington, VA 22202-4501

**SUBJECT: Information Submitted In Accordance with FIFRA Section 6(a)(2)**  
**Report of a study with Virkon® S (EPA Reg # 62432-1)**

To Whom It May Concern:

Antec International has recently completed a chronic trout study with Virkon® S (EPA Reg # 62432-1). This research study was conducted to support non-US use patterns for this product; it was not conducted in accordance with OPPTS guidelines, nor was it conducted under GLP.

This ecological study appears to be reportable in accordance with 40 CFR. 159.165 (b). In this study, newly hatched trout were exposed to nominal concentrations of 0, 2, 4, 6, or 8 ppm Virkon® S in a flow-through system for a period of 100 days. Transient effects were seen on growth during the first feeding stage at 4 ppm, and on mortality and growth at treatment levels of 6 and 8 ppm. There were no adverse effects noted at 2 ppm. There were no significant histological differences between the outperforming fish at 4 ppm and controls, nor between any exposed fish and controls after first feeding stage was completed.

Antec International considers the entire contents of this letter to be subject to protection afforded under FIFRA Section 10(g). Disclosure of this information may be made only in accordance with that Section.

Please call me at 302/892-8268 if you have any questions.

Sincerely,

Nancy B. Lomax  
Regulatory Manager &  
US agent, Antec International

cc: Adam Heyward, PM# 34  
cc: Mark Squire, Chief Chemist, Antec International

## DATA TRANSMITTAL DOCUMENT

Information Submitted In Accordance with FIFRA Section 6(a)(2) - Report of a study with Virkon® S (EPA Reg # 62432-1)

Antec International Ltd.  
Sudbury, Suffolk, CO10 2XD  
England

### Regulatory Action in Support of Which this Package is Submitted:

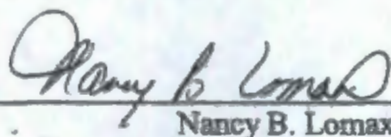
Information Submitted In Accordance with FIFRA Section 6(a)(2) - Report of a study with Virkon® S (EPA Reg # 62432-1)

Transmittal Date: August 24, 2004

### List of Submitted Studies:

<u>Data Requirement</u>	<u>Doc Number</u>	<u>Study Title</u>	<u>MRID</u>
none	DCSE-2003-008	Chronic Toxicity of Continuous Exposure to 'Virkon S for Aquaculture' to Rainbow Trout ( <i>Oncorhynchus mykiss</i> )	46349301

Submitted by:

  
Nancy B. Lomax

Date

:

Aug 26, 2004

Regulatory Manager and Agent for Antec  
International Ltd.

Telephone: 302-892-8268

Company Name: Antec International Ltd.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

January 11, 2005

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

**MEMORANDUM:**

**SUBJECT:** Screen Adverse Data [FIFRA 6(a)(2)] submission for Virkon® S, EPA  
Reg. No. 71654-6 Containing Sodium chloride and Potassium  
peroxymonosulfate

**TO:** Adam Heyward, Product Manager, Team 34  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

**FROM:** Srinivas Gowda, Microbiologist/Chemist *Srinivas Gowda 1/11/05*  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510C)

**THRU:** Siroos Mostaghimi, Acting Team Leader, Team One *Siroos - Mostaghimi*  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510C)

Norm Cook, Chief *Norm Cook*  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510C)

**DP Barcode:** D311802  
**Decision #:** 352289  
**Case Type:** Adverse Data 6(a)(2)  
**PC Codes:** 013905 & 063604  
**Chemical Names:**  
Sodium Chloride  
Potassium peroxymonosulfate

**EPA Reg. No.:** 71654-6  
**MRID No.:** 463493-01  
**Data Submitter:** DuPont Chemical  
**CAS#:** 7647-14-5 (Sodium Chloride)  
10058-23-8 (Potassium peroxymonosulfate)

## **INTRODUCTION:**

DuPont Chemical Solutions Enterprises, has submitted Adverse Data (Chronic Trout Study) in Accordance with FIFRA Section 6(a)(2) for Virkon® S (EPA Reg. No. 71654-6). 6(a)(2) Coordinator, Sharon Carlisle, requests RASSB to screen and make a determination whether the package needs to be expedited quickly as a 6(a)(2) submission. The submitted adverse data (Chronic Trout Study) has undergone review by Srinivas Gowda of Antimicrobials Division's Risk Assessment and Science Support Branch.

## **RECOMMENDATIONS:**

The submitted Adverse Data (Chronic Trout Study) under the MRID No. 463493-01 does not qualify as a 6(a)(2) submission. Risk Assessment and Science Support Branch recommends that the Chronic Trout Study for Virkon® S, EPA Reg. No. 71654-6, must be rerouted to RASSB for review under a miscellaneous (400) PRAT Code and revised due date.



**TASK ASSIGNMENT FORM**  
**Antimicrobial Division/Regulatory Management Branch II**

<b>A</b>	Completed by Product Manager						
PRODUCT REVIEWER: <u>L McKeivn</u>					RMB <u>II</u> TEAM <u>34</u>		
Description of Action:					EPA File Symbol/Reg No.: <u>62432-1</u>		
Decision No. <u>346777</u>		Submission No. <u>1764786</u>		Fee for Service Action Code: _____			
FQPA Action Code: <u>332</u>		Non-FQPA Action Code: _____		Fee for Service Fee: \$ _____			
	MONTH	DAY	YEAR				
APPLICATION DATE	<u>07</u>	<u>09</u>	<u>2004</u>				
EPA DATE	<u>07</u>	<u>12</u>	<u>2004</u>				
REVIEWER ASSIGNED DATE	<u>07</u>	<u>24</u>	<u>2004</u>				
DATE DUE TO PM	<u>08</u>	<u>06</u>	<u>2004</u>				
DATE DUE OUT OF AGENCY	<u>08</u>	<u>11</u>	<u>2004</u>				
Type of Data:	Product Chemistry <input type="checkbox"/>	Acute Toxicology <input type="checkbox"/>	Efficacy <input type="checkbox"/>	Environmental Fate <input type="checkbox"/>	Ecological Effects <input type="checkbox"/>	Chronic Toxicology <input type="checkbox"/>	Exposure <input type="checkbox"/>
<p>COMMENTS:      <u>NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM.</u></p>							
<p>DP Barcode No(s): _____</p>							
<b>B</b>	For Arctic Slope Contract Only						
Contractor: Arctic Slope			Contract No.: 0332		ARCTIC SLOPE/MANAGER		
Draft Task: Signature _____ (Est. hrs)			Final Task: Signature _____ (Total hrs)				
<p>Reviewer's Comments:</p>							
Response Code: <u>17</u>				Response Date: <u>8/4/04</u>		27	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**August 11, 2004**

Jeff Jones, Agent for  
**Antec International, Ltd.**  
7910 Woodmont Ave., Suite 1000  
Bethesda, MD 20814

Subject: Notification Application Per PR Notice 98-10  
**Virkon S**  
EPA Registration No.62432-1  
Application Dated July 9, 2004

Dear Mr. Jones:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

**Proposed Notification:**

- Adding effluent discharge labeling statement

**General Comment:**

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable and a copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422, or Lisa McKelvin at (703) 308-7496.

Sincerely,

*Lisa McKelvin*  
Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510C)





July 9, 2004

NOTIFICATION  
Date Reviewed: 8-4-04  
Reviewed By: J. McKelvin

Document Processing Desk (NOTIF)  
Office of Pesticide Programs  
US EPA  
1801 Bell Street  
Arlington, VA 22202

Re: Virkon S; EPA Reg. No. 62432-1; Notification of addition of effluent discharge labeling statement pursuant to PR Notice 95-1

Dear Sir or Madam:

I am notifying the Agency of the addition of the required effluent discharge labeling statement pursuant to PR Notice 95-1 to the Virkon S label. Previously, Virkon S has not been distributed in large containers, but it will be in the future. Accordingly I am adding the required effluent discharge statement. Attached please find the following documents supporting this notification:

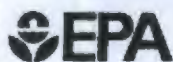
- Application for Pesticide Registration (EPA Form 8570-1)
- Proposed labeling (5 copies)
- Current stamped label

If you have questions regarding this submission, please contact me.

Sincerely,

T. Jeffrey Jones, Agent  
Antec International Ltd.

Attachments



United States  
Environmental Protection Agency  
Washington, DC 20480

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

295765

## Application for Pesticide - Section I

1. Company/Product Number 62432-1	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Virkon S	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd. c/o Delta Analytical Corp. 7910 Woodmont Ave., Suite 1000 Bethesda, MD 20814  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____  Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	<b>NOTIFICATION</b> Date Reviewed: 8-4-04 Reviewed By: L. McKelvin
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification pursuant to PR Notice 95-1 adding effluent discharge labeling statement.

I certify that this notification is consistent with PR Notice 95-1 and EPA regulations at 40 CFR 152.46 and that no other changes have been made to the labeling of this product. I further understand that if this notification is not consistent with the terms of PR Notice 95-1 and 40 CFR 152.46, then this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Jeff Jones		Title Agent, Antec International Ltd.		Telephone No. (Include Area Code) 301 652 5495	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped) 
2. Signature 		3. Title Agent, Antec International Ltd.			
4. Typed Name Jeff Jones		5. Date July 9, 2004			



**MASTER LABEL**

**Virkon® S**  
**BROAD SPECTRUM DISINFECTANT**

**NOTIFICATION**  
 Date Reviewed: 8-4-04  
 Reviewed By: L. McRELVIN

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities

Effective against Viruses  
 (including CANINE PARVOVIRUS) • Bacteria • Fungi

For Use in Emergency Disease Control

For use in Cleaning and Disinfecting Institutional and Service Facilities including stores, factories, schools, hotels, offices, ships, planes, transportation terminals, supermarkets and food warehouses.

For Use in Emergency Response and On-site Cleanup (emergency response calls, crime scenes, traffic accidents, fires, flood, natural and other disasters) e.g. cars, trucks, ambulances, and similar emergency apparatus, tires, wheels, floors, walls, ceilings, paved surfaces; and equipment such as SCBA, coats, boots, hats, masks, gloves, axes, Jaws of Life and similar emergency.

For Use in Greenhouses, Horticulture, and Aquaculture

**ACTIVE INGREDIENTS:**

Potassium peroxymonosulfate.....	20.4%
Sodium Chloride.....	1.5%
OTHER INGREDIENTS.....	<u>78.1%</u>
TOTAL.....	100.00%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

See [Back] [Side] Panel[s] [Inside Booklet] for Additional Precautions

Front Panel Continued

**FIRST AID**

**Have the product container or label with you when calling a poison control center or doctor, or going for treatment.**

**If Swallowed:**

- Call Poison Control Center or doctor immediately for treatment advice.
- Have Person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor
- Do not give anything by mouth to an unconscious person

**If Inhaled:**

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a Poison Control Center or doctor for further treatment advice.

**If in Eyes:**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present after 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for further treatment advice.

**If on Skin:**

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center or doctor for further treatment advice.

**Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage.

**Emergency Contact Number:** 011 44 1787 377305

\_\_\_ lbs. (\_\_\_) Net Weight

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

**Antec**  
**International**  
 LEADERS IN BIOSECURITY

**Manufactured By:**  
**ANTEC INTERNATIONAL LTD.**  
 Windham Road, Chilton Industrial Estates  
 Sudbury Suffolk CO10 6XD, England

Virkon® S is a registered trademark of and manufactured by Antec International Limited  
 US Patent No. 4822512



[Comment: The list of claims (sites) under "EFFECTIVE AGAINST" may be placed in any order as long as each subheading and its contents remains intact.]

## **EFFECTIVE AGAINST THE FOLLOWING ~~ANIMAL HEALTH~~ PATHOGENS:**

### **ANIMAL AND ZONOTIC PATHOGENS**

#### **BACTERIA**

Actinobacillus pleuropneumonia  
 Bacillus cereus  
 Bordetella avium  
 Bordetella bronchiseptica  
 Campylobacter pyloridis  
 Clostridium perfringens  
 Dermatophilus congolensis  
 Escherichia coli  
 Erysipelothrix rhusiopathiae  
 Fistulous withers (Poll Evil)  
 Haemophilus somnus  
 Klebsiella pneumoniae  
 Moraxella bovis (Pink Eye)  
 Mycobacterium bovis  
 Mycoplasma gallisepticum  
 Mycoplasma mycoides  
 Pasteurella multocida  
 Pseudomonas aeruginosa  
 Pseudomonas mallei (Glanders)  
 Pseudomonas vulgaris  
 Salmonella choleraesuis  
 Salmonella typhimurium  
 Staphylococcus aureus  
 Staphylococcus epidermidis  
 Streptococcus equi (Strangles)  
 Streptococcus pyogenes  
 Streptococcus suis  
 Taylorella equigenitalis  
 Treponema hyodysenteriae

#### **VIRUSES**

Adenovirus Pneumonia  
 African Horse Sickness Virus  
 African Swine Fever Virus  
 Avian Influenza Virus  
 Avian Laryngotracheitis Virus  
 Bovine Adenovirus Type 4  
 Bovine Polyoma Virus  
 Bovine Pseudocowpox Virus  
 Bovine Viral Diarrhea Virus  
 Calf Rotavirus  
 Canine Adenovirus  
 Canine Coronavirus  
 Canine Parainfluenza Virus  
 Canine Parvovirus  
 Chicken Anemia Virus  
 Coital Exanthema Virus  
 Distemper Virus  
 Duck Adenovirus  
 Duck Enteritis Virus  
 Egg Drop Syndrome Adenovirus  
 Equine Infectious Anemia Virus (Swamp Fever)  
 Equine Arteritis Virus  
 Equine Herpes Virus (Type 1)  
 Herpes Virus Equine (Type 3)  
 Hog Cholera Virus  
 Equine Contagious Abortion Virus  
 Equine Papillomatosis Virus  
 Equine Influenza Virus (Type A)  
 Equine Influenza Virus (The Cough)  
 Feline Calicivirus  
 Feline Herpes Virus  
 Feline Infectious Peritonitis Virus

Feline Panleukopenia Virus  
 Feline Parvovirus  
 Feline Rhinotracheitis Virus  
 Foot and Mouth Disease Virus  
 Infectious Bronchitis Virus  
 Infectious Bursal Disease Virus  
 Infectious Canine Hepatitis Virus  
 Infectious Pancreatic Necrosis Virus  
 Infectious Salmon Anaemia Virus  
 Infective Bovine Rhinotracheitis Virus  
 Leptospira Canicola Virus  
 Maedi- Visna Virus  
 Marek's Disease Virus  
 Newcastle Disease Virus  
 PCV2 Virus (PMWS)  
 Porcine Parvovirus  
 Porcine Reproductive and Respiratory  
 Syndrome Virus (PRRS)  
 Pseudorabies Virus (Aujeszky's Disease)  
 Rotaviral Diarrhea Virus  
 Snakehead rhabdovirus  
 SV40 Virus  
 Swine Influenza Virus  
 Transmissible Gastroenteritis Virus (TGE)  
 Turkey Herpes Virus  
 Turkey Rhinotracheitis Virus  
 Vesicular Stomatitis Virus

## FUNGI

Aspergillus fumigatus  
 Candida albicans  
 Fusarium moniliforme  
 Microsporum canis  
 Trichophyton spp. (Ringworm)  
 Trichophyton spp. (Mud Fever)

## PLANT PATHOGENS

Alternaria solani  
 Botrytis cinera  
 Colletotrichum coccodes  
 Didymella bryoniae  
 Fusarium oxysporum  
 Fusarium solani  
 Penicillium oxalicum  
 Phomopsis sclerotioides  
 Pyrenochaeta lycoopersici  
 Pythium aphanidermatum  
 Rhizoctonia solani  
 Sclerotinia sclerotiorum  
 Thielaviopsis basicola  
 Verticillium dahliae

## EFFECTIVE AGAINST THE FOLLOWING HUMAN HEALTH PATHOGENS

Human Immuno-Deficiency Virus (HIV) Type 1 (on hard non-porous surfaces), Streptococcus pyogenes, Campylobacter pyloridis, klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, and Candida albicans.



## **PRECAUTIONARY STATEMENTS**

### **HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER.** Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. **Corrosive statement refers to powder only not in use solution.**

[note to reviewer: Effluent discharge statement to be included for package sizes of greater than or equal to 5 gallons (liquid) or 50 pounds (solid, dry weight), in accordance with PR notice 95-1]

### **ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

[Comment: The instructions under "DIRECTIONS FOR USE" may be placed in any order as long as they remain a continuous section on the label.]

### **BROAD SPECTRUM DISINFECTANT**

Virkon<sup>®</sup> S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy of the 1% solution was determined in the presence of 400 ppm AOAC hard water and 5% organic material. Virkon<sup>®</sup> S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water. Apply a 0.5% (1:200) solution for routine sanitation.

### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

### **GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES**

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.
2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.



5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.
8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

This powder formula is easily diluted for use in manual or machine operations.

#### **Virkon® S DILUTION CHART**

*Fill container with desired amount of water and add Virkon® S powder to achieve recommended solution concentration.*

<b>Quantity of Water</b>	<b>0.5% Solution</b>	<b>1% Solution</b>	<b>2% Solution</b>
<b>1 Quart</b>	<b>0.15 ounces</b>	<b>0.3 ounces</b>	<b>0.7 ounces</b>
<b>1 Gallon</b>	<b>0.65 ounces</b>	<b>1.3 ounces</b>	<b>2.7 ounces</b>
<b>10 Gallons</b>	<b>6.7 ounces</b>	<b>13.4 ounces</b>	<b>26.7 ounces</b>
<b>50 Gallons</b>	<b>33.4 ounces</b>	<b>66.8 ounces</b>	<b>133.5 ounces</b>

*Measuring cup provided.*

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

#### **POULTRY [PRODUCTION] [AND RATITE PRODUCTION]**

[CONTROLS: Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*. Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium* and *Mycoplasma gallisepticum*.]

HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.



Virkon<sup>®</sup> S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

**BROILER/BREEDER HOUSES:** Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon<sup>®</sup> S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon<sup>®</sup> S. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

**FOR AIR SANITIZING:** Use Virkon<sup>®</sup> S at 0.5-1% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

**PROCESSING PLANTS:** Spray Virkon<sup>®</sup> S at 1% solution to disinfect and clean walls, ceilings and floors.

## SWINE PRODUCTION

[CONTROLS: Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine Fever and Foot and Mouth Disease. Bacteria of Pleuropneumonia, Treponema hyodysenteriae, and Clostridium perfringens. Fungi: Fusarium moniliforme.]

Follow General Instructions to remove swine and preclean area to be treated. Virkon<sup>®</sup> S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon<sup>®</sup> S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

## EQUINE PRODUCTION

**BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION**

[CONTROLS: Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis. Bacterial: Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders). Fungi: Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), and Fusarium moniliforme.]

**APPLICATIONS:** For cleaning and disinfecting all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.



**USES:**

**Stables, Horse Boxes, Box Stalls, Tack ,Equipment, and Feed Rooms:** Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon<sub>®</sub> S solution. Rinse with clean water.

**Blankets, Saddle Pads and Rugs:** Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

**Aerial Spraying to control airborne diseases:** Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon<sub>®</sub> S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.

**BOVINE PRODUCTION**

[CONTROLS: Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies and Foot and Mouth Disease; Bacteria of *Maraxella bovis*, *Haemophilus somnus* and *Mycobacterium bovis*; Fungi of *Fusarium moniliforme*.]

Follow General Instructions to remove livestock and preclean area to be treated. A 1% solution of Virkon<sub>®</sub> S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

**COMPANION ANIMALS**

[CONTROLS: Viruses Canine Parvovirus, Distemper, *Leptospira canicola*, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of *Staphylococcus aureus*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*; Fungi of *Microsporum canis*.]

[APPLICATIONS] A 1% solution of Virkon<sub>®</sub> S is recommended as a "one step" cleaning and disinfecting procedure for all surfaces, equipment, instruments, utensils and cages [caging systems] within [associated with] Veterinary Medical Hospitals, infectious disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon<sub>®</sub> S for long periods - 10 minutes is maximum contact time.

**GREENHOUSES AND HORTICULTURE**

Virkon<sub>®</sub> S is intended to disinfect inanimate environmental surfaces, glasshouse structures, equipment, utensils, trays, containers, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.



Remove all crop debris, strings and other deposits from structures, empty trays and pots. Power wash all the dust off the covering and superstructure and let dry. Using a sprayer or fogger saturate all surfaces with a 1% solution of Virkon® S. Let air dry.

Virkon® S may also be used to disinfect irrigation tanks and lines. Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon® S at 0.5-1%% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

## AQUACULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

## EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

**CONTROLS:** OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus.

A 1% solution of Virkon® S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).



Spray Virkon<sup>®</sup> S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon<sup>®</sup> S for long periods - 10 minutes is maximum contact time.

### INSTITUTIONAL AND SERVICE FACILITIES (HUMAN HEALTH)

**CONTROLS:** Human Immuno-Deficiency Virus (HIV) Type 1 (on hard non-porous surfaces), *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Candida albicans*.

With Virkon<sup>®</sup> S, only one product is needed to clean and disinfect all surfaces except acid-sensitive surfaces such as copper, brass, or aluminum. Do not use Virkon S on these acid-sensitive surfaces. Avoid splashing Virkon<sup>®</sup> S solution on textiles or carpets. Virkon<sup>®</sup> S may be used on carpeting or other textiles only if area is tested for color fastness before use and treated area vacuumed when dry.

**Cleaning and Disinfecting Non-Food Contact Surfaces:** Remove gross dirt and use 1.0% Virkon<sup>®</sup> S solution prepared according to the Dilution Chart below. Apply to surface using a mop, sponge, brushes or spray device until the surface is visibly clean. Air dry. In cases of fungal or viral contamination of non-food contact surfaces, follow these instructions substituting a 2.0% Virkon<sup>®</sup> S solution.

**Sanitizing Toilet Bowls.** After flushing, sprinkle 1 oz. Virkon<sup>®</sup> S powder around the bowl, scrub with a brush, and leave for 10 minutes. Flush.

**Cleaning and Disinfecting Manikins Used in CPR Training:** Manikins should be cleaned as soon as possible at the end of each class to avoid drying of contaminants on surfaces. Disassemble the manikin as directed by the manufacturer's instructions. Thoroughly wash all internal and external surfaces and reusable protective face shields with a brush using a 1% Virkon<sup>®</sup> S solution. Let stand for 10 minutes and rinse with potable water.

**Cleaning and Disinfecting Hard, Non-porous Surfaces Suspected of HIV Type 1 Contamination:** Cover heavy spillage of body fluids with Virkon<sup>®</sup> S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste. Prepare 2% Virkon<sup>®</sup> S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

### EMERGENCY RESPONSE AND ON-SITE CLEANUP

Cover heavy spillage of body fluids with Virkon<sup>®</sup> S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste.



Prepare 2% Virkon<sup>®</sup> S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

### **STORAGE AND DISPOSAL**

**STORAGE:** Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

**DISPOSAL:** Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals.

# PM WORK ASSIGNMENT SHEET

DECISION \_\_\_\_\_

PM 34

DESCRIPTION OF ACTION: \_\_\_\_\_

SUBMISSION BAR CODE: S 745509

PRODUCT REVIEWER: Renae

FILE SYMBOL/REG NO.: 62432-1

FQPA ACTION CODE: 307

NON-FQPA ACTION CODE: \_\_\_\_\_

AMOUNT OF TIME TO COMPLETE TASK (ASRC only)	HOURS _____
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	MONTH	DAY	YEAR
APPLICATION DATE	08	21	03
EPA PIN DATE	08	25	03
REVIEWER ASSIGNED DATE	08	28	03
DATE DUE OUT OF AGENCY			

## TYPE OF DATA

Product Chemistry: ☐

Product Toxicology: ☐

Efficacy: ☒

RASSB: ☐

HED TOX ☐

ENVIRONMENTAL FATE ☐

FISH/WILDLIFE ☐

Other ☐ \_\_\_\_\_

COMMENTS:

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JACKET(S)/FILE SHOULD BE SUBMITTED WITH YOUR LETTERS FOR SIGNATURE

RESPONSE CODE: 11 RESPONSE DATE: 10 / 15 / 03  
MO Day Year



**DATA PACKAGE BEAN SHEET**

Date: 26-Apr-2005

Page 1 of 2

**\*\*\* Registration Information \*\*\***

Registration: 71654-6 - VIRKON S

Company: 71654 - E.I. DUPONT DE NEMOURS AND COMPANY

Risk Manager: RM 34 - Adam Heyward - (703) 308-6422 Room# CM-2 308B

Risk Manager Reviewer: Sharon Carlisle SCARLISL

Sent Date: 31-Dec-2003

Calculated Due Date: 16-Jan-2004

Edited Due Date: \_\_\_\_\_

Type of Registration: Product Registration - Section 3

Action Desc: (405) ADVERSE DATA (6A2);

Ingredients: 013905, Sodium chloride(1.5%)

063604, Potassium peroxydisulfate(20.4%)

**\*\*\* Data Package Information \*\*\***Expedite: ☐ Yes ☒ No

Date Sent: 26-Feb-2004

Due Back: \_\_\_\_\_

DP Ingredient: 013905, Sodium chloride

063604, Potassium peroxydisulfate

DP Title: \_\_\_\_\_

CSF Included: ☐ Yes ☒ NoLabel Included: ☐ Yes ☒ No

Parent DP #: \_\_\_\_\_

**Assigned To****Date In****Date Out**

Organization: AD / RASSB

01-Mar-2004

25-Mar-2004

Administrative Due Date: 22-Mar-2004

Team Name: RASSB2

01-Mar-2004

25-Mar-2004

Negotiated Due Date: \_\_\_\_\_

Reviewer Name: Elkassabany, Nader

01-Mar-2004

25-Mar-2004

Projected Completion Date: \_\_\_\_\_

Contractor Name: \_\_\_\_\_

**\*\*\* Studies Sent for Review \*\*\***

No Studies

**\*\*\* Additional Data Package for this Decision \*\*\***

Printed on Page 2

**\*\*\* Data Package Instructions \*\*\***

RASSB: Please review the attached data MRID#s 461190-01 thru -12



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

**MEMORANDUM**

**Subject:** 6 (a)(2) Screening for Sodium chloride (1.5%), Potassium peroxymonosulfate (20.4%)

EPA Reg:62432-1

**Sodium chloride (1.5%), Potassium peroxymonosulfate (20.4%)**

DP Barcodes: D299148

PC code: 013905, 063604

**From:** Nader Elkassabany, Team Leader *Nader Elkassabany 3/31/04*  
Risk Assessment and Science Support Branch (RASSB), Antimicrobials Division (AD)[7510C]

**To:** Adam Heyward, PM 34  
Sharon Carlisle, PM Team Reviewer  
Regulatory Management Branch  
Antimicrobials Division [7510C]

**Thru:** Norm Cook, Chief, RASSB/AD [7510C]

**Applicant:** ANTEC INTERNATIONAL LTD

**ACTION REQUESTED:** Review the attached submission for 6 (a)(2) screening, MRID 46119001, 46119002, 46119003, 46119004, 46119005, 46119006, 46119007, 46119008, 46119009, 461190010, 461190011, and 461190012.

**CONCLUSIONS:** The submission of the studies above does not qualify as a 6(a)2 submission and an expedited review is not necessary.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

October 15, 2003

T. Jeffrey Jones, Agent for  
**Antec International Ltd.**  
c/o Delta Analytical Corporation  
7910 Woodmont Avenue, Suite 1000  
Bethesda, MD 20814

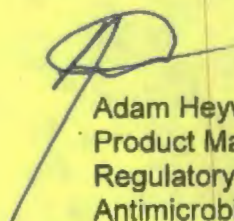
Dear Mr. Jones:

Subject: **Virkon S**  
EPA Registration No. 62432-1  
Application dated August 21, 2003

This letter is in response to your letter dated August 21, 2003 regarding the organism Rhabdovirus carpio (Spring viremia of carp virus) (SVCV). The Agency agrees that Rhabdovirus carpio, is not a public health threat. However, SVCV is on the OEI List B because of its socio-economic importance. Before the Agency would consider this claim, you must provide efficacy data for SVCV because the Agency is requiring data for the organisms on OEI's List.

Should you have any questions concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at 703 308-7003.

Sincerely,

  
Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

September 9, 2003

**MEMORANDUM:**

**Subject:** Efficacy Review for EPA Reg. No.: 62432-1, "Virkon S"  
DP Barcode: D293258  
Case No: 013905

**From:** Emily Mitchell, M.S., Team Leader *Emily Mitchell 9/10/03*  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510C)

**To:** Adam Heyward PM34/Renae Whitaker  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

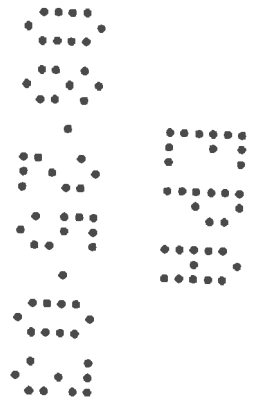
**Applicant:** Antec International LTD  
7910 Woodmont Ave., Suite 1000  
Bethesda, MD 20814

**Formulation From Label:**

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Potassium peroxymonosulfate.....	20.4%
Sodium Chloride.....	1.5%
<u>Inert Ingredient(s)</u> .....	<u>78.1%</u>
Total .....	100.0%



**PM: The Registrant is correct, SVCV is on the OEI List B because of its socio-economic importance. It is not a public health threat. However, the registrant must provide efficacy data for SVCV because the Agency is requiring data for the organisms on OEI's List for the reason mentioned above.**



August 21, 2003

Mr. Adam Heyward, PM #34  
Antimicrobials Branch  
US EPA  
Washington, DC 20460

Subject: Virkon S; EPA Reg. No. 62432-1; Your Letter Dated August 12, 2003

Dear Adam:

Thank you for your letter of August 12, 2003 granting the "Oregon" amendment to the Virkon S label. I am writing in response to your denial of the *Rhabdovirus carpio* (Spring viremia of carp virus (SVCV)) claim based on the assertion that SVCV is a public health organism. In conversation with you and Renae Whittaker, I learned that the Agency has concluded that SVCV is a public health organism by virtue of its entry on OIE List B. List B enumerates "[t]ransmissible diseases that are considered to be of socio-economic and/or [emphasis added] public health importance." Based on the information I discuss below, SVCV is listed on OIE List B because of its socio-economic importance, not because it poses a public health threat. Accordingly, I am requesting that you reconsider your denial of this claim on an expedited basis. Notwithstanding this request, Antec is prepared to submit SVCV efficacy data.

Supporting the argument that SVCV is listed on List B because of its socio-economic importance, I note that it is entered in a list of "fish diseases." By contrast, List B also includes a sub-category for "multiple species diseases." SVCV is not included in this subcategory.

On the OIE website, Professor Barry Hill of The Centre for Environment, Fisheries, and Aquaculture Sciences (CEFAS) in the United Kingdom is listed as the "expert" on SVCV. I am attaching a recent communication from Professor Hill stating that he is "aware of no scientific evidence, or even any suggestion, that SVC virus is a zoonotic agent." Professor Hill continues, "I can't understand why anyone should imagine it might be given its limited host range in fish and its ceiling temperature for growth being in the 20sC which means it can't replicate at 37C."



Finally, I am also including an APHIS factsheet on SVCV prepared by the Veterinary Services unit. The factsheet states "[t]here has never been a single report of humans being infected with the SVC virus either from contact or from eating an infected fish."

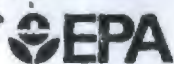
In view of this strong evidence that SVCV is not a public health organism, I ask that you approve the attached label including the appropriate claim immediately. Let me know if you would still like to review efficacy data as a condition of granting that claim in the interim.

Thanks for your assistance.

Sincerely,



T. Jeffrey Jones, Agent  
Antec International Ltd.  
Enclosures



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

281398

## Application for Pesticide - Section I

1. Company/Product Number 62432-1	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Virkon S	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd. c/o Delta Analytical Corp. 7910 Woodmont Ave., Suite 1000 Bethesda, MD 20814		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____
<input type="checkbox"/> Check if this is a new address		

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>12 Aug 03</u>	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Notification: Use additional page(s) if necessary. (For section I and Section II.)

Notification of addition of pest, Rhabdovirus carpio (spring viremia of carp (SVC)). This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 USC Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Notification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Jeff Jones	Title Agent, Antec International Ltd.	Telephone No. (include Area Code) 301 652 5495	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped) 
2. Signature 	3. Title Agent, Antec International Ltd.		
4. Typed Name Jeff Jones	5. Date 21 August 2003		



**Master Label**

**Virkon® S**  
**BROAD SPECTRUM DISINFECTANT**

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities (OPT.)

Effective against Viruses  
(including CANINE PARVOVIRUS) • Bacteria • Fungi

For Use in Emergency Disease Control (OPT.)

For use in Cleaning and Disinfecting Institutional and Service Facilities including stores, factories, schools, hotels, offices, ships, planes, transportation terminals, supermarkets and food warehouses. (OPT.)

For Use in Emergency Response and On-site Cleanup (emergency response calls, crime scenes, traffic accidents, fires, flood, natural and other disasters) e.g. cars, trucks, ambulances, and similar emergency apparatus, tires, wheels, floors, walls, ceilings, paved surfaces; and equipment such as SCBA, coats, boots, hats, masks, gloves, axes, Jaws of Life and similar emergency equipment. (OPT.)

For Use in Greenhouses, Horticulture, and Aquaculture (OPT.)

**ACTIVE INGREDIENTS:**

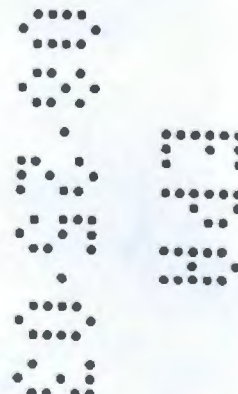
Potassium peroxymonosulfate.....	20.4%
Sodium Chloride.....	1.5%
OTHER INGREDIENTS.....	<u>78.1%</u>
TOTAL.....	100.00%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

See [Back] [Side] Panel[s] [Inside Booklet] for Additional Precautions



## Front Panel Continued

**FIRST AID**

**Have the product container or label with you when calling a poison control center or doctor, or going for treatment.**

**If Swallowed:**

- Call Poison Control Center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor
- Do not give anything by mouth to an unconscious person

**If Inhaled:**

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a Poison Control Center or doctor for further treatment advice.

**If in Eyes:**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present after 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for further treatment advice.

**If on Skin:**

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center or doctor for further treatment advice.

**Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage.

\_\_\_ lbs. (\_\_\_) Net Weight

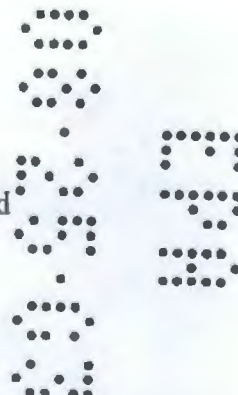
EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

**Antec**  
**International**  
 LEADERS IN BIOSECURITY

**Manufactured By:**  
**ANTEC INTERNATIONAL LTD.**  
 Windham Road, Chilton Industrial Estates  
 Sudbury Suffolk C010 2XD, England

Virkon® S is a registered trademark of and manufactured by Antec International Limited  
 US Patent No. 4822512





[Comment: The list of claims (sites) under "EFFECTIVE AGAINST" may be placed in any order as long as each subheading and its contents remains intact.]

## EFFECTIVE AGAINST THE FOLLOWING PATHOGENS:

### ANIMAL AND ZOONOTIC PATHOGENS

#### BACTERIA

Actinobacillus pleuropneumonia  
Bordetella avium  
Bordetella bronchiseptica  
Campylobacter pyloridis  
Clostridium perfringens  
Dermatophilus congolensis  
Escherichia coli  
Fistulous withers (Poll Evil)  
Haemophilus somnus  
Klebsiella pneumoniae  
Moraxella bovis (Pink Eye)  
Mycobacterium bovis  
Mycoplasma gallisepticum  
Mycoplasma mycoides  
Pasteurella multocida  
Pseudomonas aeruginosa  
Pseudomonas mallei (Glanders)  
Pseudomonas vulgaris  
Salmonella choleraesuis  
Salmonella typhimurium  
Staphylococcus aureus  
Staphylococcus epidermidis  
Streptococcus equi (Strangles)  
Streptococcus pyogenes  
Streptococcus suis  
Taylorella equigenitalis  
Treponema hyodysenteriae

#### VIRUSES

Adenovirus Pneumonia  
African Horse Sickness Virus  
African Swine Fever Virus  
Avian Influenza Virus  
Avian Laryngotracheitis Virus

Bovine Adenovirus Type 4  
Bovine Polyoma Virus  
Bovine Pseudocowpox Virus  
Bovine Viral Diarrhea Virus  
Calf Rotavirus  
Canine Adenovirus  
Canine Coronavirus  
Canine Parainfluenza Virus  
Canine Parvovirus  
Chicken Anemia Virus  
Coital Exanthema Virus  
Distemper Virus  
Duck Adenovirus  
Duck Enteritis Virus  
Egg Drop Syndrome Adenovirus  
Equine Infectious Anemia Virus (Swamp Fever)  
Equine Arteritis Virus  
Equine Herpes Virus (Type 1)  
Herpes Virus Equine (Type 3)  
Hog Cholera Virus  
Equine Contagious Abortion Virus  
Equine Papillomatosis Virus  
Equine Influenza Virus (Type A)  
Equine Influenza Virus (The Cough)  
Feline Calicivirus  
Feline Herpes Virus  
Feline Infectious Peritonitis Virus  
Feline Panleukopenia Virus  
Feline Parvovirus  
Feline Rhinotracheitis Virus  
Foot and Mouth Disease Virus  
Infectious Bronchitis Virus  
Infectious Bursal Disease Virus  
Infectious Canine Hepatitis Virus  
Infectious Pancreatic Necrosis Virus  
Infectious Salmon Anaemia Virus  
Infective Bovine Rhinotracheitis Virus

Leptospira Canicola Virus  
 Maedi- Visna Virus  
 Marek's Disease Virus  
 Newcastle Disease Virus  
 PCV2 Virus (PMWS)  
 Porcine Parvovirus  
 Porcine Reproductive and Respiratory  
 Syndrome Virus (PRRS)  
 Pseudorabies Virus (Aujeszky's Disease)  
*Rhabdovirus carpio* (Spring Viremia of Carp  
 (SVC) virus)  
 Rotaviral Diarrhea Virus  
 Snakehead rhabdovirus  
 SV40 Virus  
 Swine Influenza Virus  
 Transmissible Gastroenteritis Virus (TGE)  
 Turkey Herpes Virus  
 Turkey Rhinotracheitis Virus  
 Vesicular Stomatitis Virus

## PLANT PATHOGENS

Alternaria solani  
 Botrytis cinera  
 Colletotrichum coccodes  
 Didymella bryoniae  
 Fusarium oxysporum  
 Fusarium solani  
 Penicillium oxalicum  
 Phomopsis sclerotoides  
 Pyrenochaeta lycoopersici  
 Pythium aphanidermatum  
 Rhizoctonia solani  
 Sclerotinia sclerotiorum  
 Thielaviopsis basicola  
 Verticillium dahliae

## FUNGI

Aspergillus fumigatus  
 Candida albicans  
 Fusarium moniliforme  
 Microsporum canis  
 Trichophyton spp. (Ringworm)  
 Trichophyton spp. (Mud Fever)

## EFFECTIVE AGAINST THE FOLLOWING HUMAN HEALTH PATHOGENS

Human Immuno-Deficiency Virus (HIV) Type 1 (on hard, non-porous surfaces), Streptococcus pyogenes, Campylobacter pyloridis, klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, and Candida albicans.

## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER.** Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. **Corrosive statement refers to powder only not in use solution.**



[Comment: The instructions under "DIRECTIONS FOR USE" may be placed in any order as long as they remain a continuous section on the label.]

### BROAD SPECTRUM DISINFECTANT

Virkon® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy of the 1% solution was determined in the presence of 400 ppm AOAC hard water and 5% organic material. Virkon® S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water. Apply a 0.5% (1:200) solution for routine sanitation.

### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

### GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.
2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.
8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

This powder formula is easily diluted for use in manual or machine operations.

### Virkon® S DILUTION CHART

*Fill container with desired amount of water and add Virkon® S powder to achieve recommended solution concentration.*

<i>Quantity of Water</i>	<i>0.5% Solution</i>	<i>1% Solution</i>	<i>2% Solution</i>
<i>1 Quart</i>	<i>0.15 ounces</i>	<i>0.3 ounces</i>	<i>0.7 ounces</i>
<i>1 Gallon</i>	<i>0.65 ounces</i>	<i>1.3 ounces</i>	<i>2.7 ounces</i>



<i>10 Gallons</i>	<i>6.7 ounces</i>	<i>13.4 ounces</i>	<i>26.7 ounces</i>
<i>50 Gallons</i>	<i>33.4 ounces</i>	<i>66.8 ounces</i>	<i>133.5 ounces</i>

*Measuring cup provided.*

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

### POULTRY [PRODUCTION] [AND RATITE PRODUCTION]

[CONTROLS: Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts) - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*. Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium* and *Mycoplasma gallisepticum*.] (OPT.)

HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.

Virkon® S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: Use Virkon® S at 0.5-1% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use. PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors.

### SWINE PRODUCTION

[CONTROLS: Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine Fever and Foot and Mouth Disease. Bacteria of *Pleuropneumonia*, *Treponema hyodysenteriae*, and *Clostridium perfringens*. Fungi: *Fusarium moniliforme*.] (OPT.)

Follow General Instructions to remove swine and preclean area to be treated. Virkon® S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.



Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

## EQUINE PRODUCTION

### BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

[CONTROLS: Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis. Bacterial: Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders). Fungi: Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), and Fusarium moniliforme.] (OPT.)

APPLICATIONS: For cleaning and disinfecting all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

#### USES:

Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution. Rinse with clean water.

Blankets, Saddle Pads and Rugs: Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

Aerial Spraying to control airborne diseases: Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon® S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.

## BOVINE PRODUCTION

[CONTROLS: Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies and Foot and Mouth Disease; Bacteria of Maraxella bovis, Haemophilus somnus and Mycobacterium bovis; Fungi of Fusarium moniliforme.] (OPT.)

Follow General Instructions to remove livestock and preclean area to be treated. A 1% solution of Virkon® S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

## COMPANION ANIMALS



[CONTROLS: Viruses of Canine Parvovirus, Distemper, Leptospira canicola, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa; Fungi of Microsporum canis.] (OPT.)

[APPLICATIONS] A 1% solution of Virkon® S is recommended as a "one step" cleaning and disinfecting procedure for all surfaces, equipment, instruments, utensils and cages [caging systems] within [associated with] Veterinary Medical Hospitals, infectious disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

### GREENHOUSES AND HORTICULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces, glasshouse structures, equipment, utensils, trays, containers, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

Remove all crop debris, strings and other deposits from structures, empty trays and pots. Power wash all the dust off the covering and superstructure and let dry. Using a sprayer or fogger saturate all surfaces with a 1% solution of Virkon® S. Let air dry.

Virkon® S may also be used to disinfect irrigation tanks and lines. Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

### AQUACULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog



(wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

### EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

**CONTROLS:** OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus. (OPT.)

A 1% solution of Virkon® S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

### USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS

A 1% solution of Virkon S is recommended to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.



To ensure that Virkon S does not come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon S may only be applied using hand-held sprayers, sponges on other absorbent materials. Do not allow Virkon S to pool on surfaces that may be within reach of animals. Do not allow Virkon S to come into direct contact with people. Allow Virkon S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

## INSTITUTIONAL AND SERVICE FACILITIES (HUMAN HEALTH)

**CONTROLS:** Human Immuno-Deficiency Virus (HIV) Type 1 (on hard, non-porous surfaces), *Streptococcus pyogenes*, *Campylobacter pyloridis*, *klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Candida albicans*. (OPT.)

With Virkon® S, only one product is needed to clean and disinfect all surfaces except acid-sensitive surfaces such as copper, brass, or aluminum. Do not use Virkon S on these acid-sensitive surfaces. Avoid splashing Virkon® S solution on textiles or carpets. Virkon® S may be used on carpeting or other textiles only if area is tested for color fastness before use and treated area vacuumed when dry.

**Cleaning and Disinfecting Non-Food Contact Surfaces:** Remove gross dirt and use 1.0% Virkon® S solution prepared according to the Dilution Chart below. Apply to surface using a mop, sponge, brushes or spray device until the surface is visibly clean. Air dry. In cases of fungal or viral contamination of non-food contact surfaces, follow these instructions substituting a 2.0% Virkon® S solution.

**Sanitizing Toilet Bowls:** After flushing, sprinkle 1 oz. Virkon® S powder around the bowl, scrub with a brush, and leave for 10 minutes. Flush.

**Cleaning and Disinfecting Manikins Used in CPR Training:** Manikins should be cleaned as soon as possible at the end of each class to avoid drying of contaminants on surfaces. Disassemble the manikin as directed by the manufacturer's instructions. Thoroughly wash all internal and external surfaces and reusable protective face shields with a brush using a 1% Virkon® S solution. Let stand for 10 minutes and rinse with potable water.

**Cleaning and Disinfecting Hard, Non-porous Surfaces Suspected of HIV Type 1 Contamination:** Cover heavy spillage of body fluids with Virkon® S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste. Prepare 2% Virkon® S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

## EMERGENCY RESPONSE AND ON-SITE CLEANUP

Cover heavy spillage of body fluids with Virkon® S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste.



Prepare 2% Virkon® S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

#### STORAGE AND DISPOSAL

**STORAGE:** Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

**DISPOSAL:** Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals

# PM WORK ASSIGNMENT SHEET

DECISION \_\_\_\_\_

PM \_\_\_\_\_

DESCRIPTION OF ACTION: \_\_\_\_\_

SUBMISSION BAR CODE: S \_\_\_\_\_

PRODUCT REVIEWER: Adam

FILE SYMBOL/REG NO.: 62 432-1

FQPA ACTION CODE: 303

NON-FQPA ACTION CODE: \_\_\_\_\_

AMOUNT OF TIME TO COMPLETE TASK (ASRC only)

HOURS \_\_\_\_\_

	MONTH	DAY	YEAR
APPLICATION DATE	<u>07</u>	<u>30</u>	<u>03</u>
EPA PIN DATE	<u>07</u>	<u>30</u>	<u>03</u>
REVIEWER ASSIGNED DATE	<u>03</u>	<u>30</u>	<u>03</u>

## TYPE OF DATA

Product Chemistry: ☐

Product Toxicology: ☐

Efficacy: ☐

RASSB: ☐

HED TOX ☐

ENVIRONMENTAL FATE ☐

FISH/WILDLIFE ☐

Other ☐ \_\_\_\_\_

## COMMENTS:

PR Notice 2001-1: Review complete label within 30 days from Reviewer

Assignment Date: \_\_\_\_\_

Viewed by: \_\_\_\_\_

JACKET(S)/FILE SHOULD BE SUBMITTED WITH YOUR LETTERS FOR SIGNATURE

RESPONSE CODE: 17

RESPONSE DATE: 08 / 05 / 03 *letter*

MO

Day

Year

08/08/03 *in OPEN*



# PM WORK ASSIGNMENT SHEET

DECISION \_\_\_\_\_

PM \_\_\_\_\_

DESCRIPTION OF ACTION: \_\_\_\_\_

SUBMISSION BAR CODE: S \_\_\_\_\_

PRODUCT REVIEWER: 62432-1

FILE SYMBOL/REG NO.: ADAM

FQPA ACTION CODE: 302 NON-FQPA ACTION CODE: \_\_\_\_\_

AMOUNT OF TIME TO COMPLETE TASK (ASRC only)	HOURS _____
---	-------------

	MONTH	DAY	YEAR
APPLICATION DATE	05	02	03
EPA PIN DATE	05	05	03
REVIEWER ASSIGNED DATE	05	25	03

## TYPE OF DATA

Product Chemistry: ☐ Product Toxicology: ☐ Efficacy: ☐

RASSB: ☐ HED TOX ☐ ENVIRONMENTAL FATE ☐ FISH/WILDLIFE ☐

Other ☐ \_\_\_\_\_

## COMMENTS:

PR Notice 2001-1: Review complete label within 30 days from Reviewer

Assignment Date: \_\_\_\_\_

Viewed by: \_\_\_\_\_

JACKET(S)/FILE SHOULD BE SUBMITTED WITH YOUR LETTERS FOR SIGNATURE

RESPONSE CODE: 37 RESPONSE DATE: 07 / 29 / 03  
MO Day Year

*OPPTN would not let you close out with date less than date created*



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**August 5, 2003**

T. Jeffrey Jones,  
Delta Analytical Corp.  
An Agent for  
**Antec International Ltd.**  
7910 Woodmont Avenue, Suite 100  
Bethesda, MD 20814

Dear Mr. Jones:

Subject: **VIRKON S**  
EPA Registration Number 62432-1  
Application Date: May 2, 2003  
Revised Submission Date: July 30, 2003

The following amendment/labeling, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the following comments:

**Proposed amendments:**

- add uses on label for temporary confinement of animals
- additional organism claim "*Rhabdovirus carpio* (spring viremia of carp)"

**General Comments:**

I. Acceptable label language:

The revised labeling text under the subheading "***Uses in facilities used for temporary confinement of animals***" submitted in your letter of July 30, 2003 is acceptable.



II. Unacceptable claim:

The amendment to add the *Rhabdovirus carpio* organism *also known as* spring viremia of carp to the subject product labeling is not acceptable for the following reason(s):

- *Rhabdovirus carpio* is considered a public health organism. Therefore, you must submit efficacy data to support additional claim for the *Rhabdovirus carpio*.

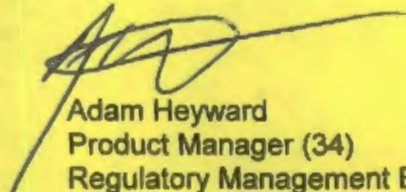
**Other comments:**

Refer to EPA letter dated July 22, 2033 for additional labeling revisions.

Submit three (3) copies of your final printed labeling bearing the revisions as stated in section I above. A copy will be stamped and return for your record.

Should you have any questions concerning this letter, please contact me at (703) 308-6422.

Sincerely,



Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

**Facsimile Message**

Total No. of Pages Including Cover: 4

July 30, 2003

**To: Adam Heyward****From: Jeff Jones****Subject: Revised Oregon amendment**

Following up on our telephone conversation this morning, attached please find a copy of the revised "Oregon amendment" language. If you discard everything after page 8 of the May 2 submission and substitute the following three pages, you will have a complete label. No other changes have been made on these pages aside from the Oregon language we discussed on our conference call.

If you need a complete label, I've emailed an electronic version this morning that was sent over after our June 10 conference call.

Let me know if you have questions or need additional information. Since this is a high priority for Oregon, I would like to send a messenger to collect the label when it is stamped. Thanks for your assistance.

Best regards,

A handwritten signature in black ink, appearing to be "J Jones", written over a horizontal line.



(wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

### EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

**CONTROLS:** OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus. (OPT.)

A 1% solution of Virkon<sup>®</sup> S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment, airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray Virkon<sup>®</sup> S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon<sup>®</sup> S for long periods - 10 minutes is maximum contact time.

### USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS

A 1% solution of Virkon S is recommended to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.



To ensure that Virkon S does not come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon S may only be applied using hand-held sprayers, sponges on other absorbent materials. Do not allow Virkon S to pool on surfaces that may be within reach of animals. Do not allow Virkon S to come into direct contact with people. Allow Virkon S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

### INSTITUTIONAL AND SERVICE FACILITIES (HUMAN HEALTH)

**CONTROLS:** Human Immuno-Deficiency Virus (HIV) Type 1 (on hard, non-porous surfaces), Streptococcus pyogenes, Campylobacter pyloridis, klebsiella pncumoniac, Eschcrichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, and Candida albicans. (OPT.)

With Virkon® S, only one product is needed to clean and disinfect all surfaces except acid-sensitive surfaces such as copper, brass, or aluminum. Do not use Virkon S on these acid-sensitive surfaces. Avoid splashing Virkon® S solution on textiles or carpets. Virkon® S may be used on carpeting or other textiles only if area is tested for color fastness before use and treated area vacuumed when dry.

**Cleaning and Disinfecting Non-Food Contact Surfaces:** Remove gross dirt and use 1.0% Virkon® S solution prepared according to the Dilution Chart below. Apply to surface using a mop, sponge, brushes or spray device until the surface is visibly clean. Air dry. In cases of fungal or viral contamination of non-food contact surfaces, follow these instructions substituting a 2.0% Virkon® S solution.

**Sanitizing Toilet Bowls:** After flushing, sprinkle 1 oz. Virkon® S powder around the bowl, scrub with a brush, and leave for 10 minutes. Flush.

**Cleaning and Disinfecting Manikins Used in CPR Training:** Manikins should be cleaned as soon as possible at the end of each class to avoid drying of contaminants on surfaces. Disassemble the manikin as directed by the manufacturer's instructions. Thoroughly wash all internal and external surfaces and reusable protective face shields with a brush using a 1% Virkon® S solution. Let stand for 10 minutes and rinse with potable water.

**Cleaning and Disinfecting Hard, Non-porous Surfaces Suspected of HIV Type 1 Contamination:** Cover heavy spillage of body fluids with Virkon® S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste. Prepare 2% Virkon® S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

### EMERGENCY RESPONSE AND ON-SITE CLEANUP

Cover heavy spillage of body fluids with Virkon® S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste.



Page 11

Prepare 2% Virkon<sup>®</sup> S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

**STORAGE AND DISPOSAL**

**STORAGE:** Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

**DISPOSAL:** Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals

\*\*\*\*\*  
\*\*\* ERROR TX REPORT \*\*\*  
\*\*\*\*\*

TX FUNCTION WAS NOT COMPLETED

TX/RX NO 0155  
CONNECTION TEL 15022672233  
SUBADDRESS  
CONNECTION ID  
ST. TIME 07/30 09:56  
USAGE T 00'00  
PGS. 0  
RESULT NG  
0 #018



United States Environmental Protection Agency  
Washington, D.C. 20460

Office of Prevention, Pesticides and Toxic Substances  
Office of Pesticide Programs  
Antimicrobial Division

FAX NUMBER (703)-

**FACSIMILE REQUEST/COVER SHEET**  
(Please type or print clearly in black ink only)

**SEND FAX TO:**

Name: SHPS, ESAFEEDS program

Office: \_\_\_\_\_

FAX Phone No. 502-267-2233

Office Phone No. \_\_\_\_\_

**FROM:**

Name: Debbie Smegap

Division/Branch: OPP/AD

Office Phone No. 703-308-075

Office Room No. \_\_\_\_\_



**Facsimile Message**

Total No. of Pages Including Cover: 2

**May 30, 2003****To:** Adam Heyward  
Connie Welch**From:** Jeff Jones**Subject:** Virkon S; EPA Reg. No. 62432-1; OPP ID # 250999; Pending amendment

Following up on a conversation with Adam, I would like to schedule a conference call next week to discuss two pending changes to the Virkon S label, one requested by APHIS (additional organism claim) and one by the Oregon Department of Agriculture (expanded use pattern). The additional organism claim is an animal health claim against Spring Viremia of Carp which could have been submitted as a notification. The purpose of the call would be to discuss the text of the proposed amendment, your thoughts on its "approvability," any adjustments you would recommend, and the timing of your review.

The expanded use pattern involves application of Virkon S in the presence of animals. Several years ago the Agency asked Antec to add a general prohibition against applying Virkon S in the presence of animals presumably to ensure that no animal exposure raising tolerance issues could occur. For the same reason, direct application to animals has never been approved.

Recently, officials of the Oregon Department of Agriculture contacted me to discuss whether the current Virkon S label would permit application in the presence of animals. We agreed it would not. The Oregon fair season begins in July and state veterinary officials fearing increased risks of spread of E. coli and animal diseases like Newcastle Disease have recommended consideration of Virkon S as a preventive measure. Responding to Oregon's inquiry I agreed to draft and submit an amendment addressing Oregon's needs. The amendment was submitted on May 2, 2003. Subsequently the Oregon folks sent me their suggested amendment language which is attached. I prefer their language because it is more specific and I suspect you will too.

Could we schedule a conference call to discuss these issues next week on either June 2<sup>nd</sup>, 4<sup>th</sup> or 5<sup>th</sup>? I can reschedule any existing commitments on those days to accommodate the time that works best for you.

Best regards,

A handwritten signature in dark ink, appearing to be "J. Jones", written in a cursive style.

7910 Woodmont Avenue Suite 1000 Bethesda, Maryland 20814  
(301) 652-5495 FAX (301) 652-5408 Email: [jjones@delta-ac.com](mailto:jjones@delta-ac.com)

## Attachment I

**Comparison of Proposal to Permit Use of Virkon S in Presence of Animals****May 2 Proposal****Fairs, Exhibitions, and Expositions**

A 1% solution of Virkon<sup>®</sup> S is recommended to clean and disinfect inanimate environmental surfaces such as pens, cages, stalls, stables, and walkways at fairs, exhibitions, and expositions. Application of Virkon S may occur in the presence of animals at these sites only, and only if care is taken to avoid intentional contact with the animals present. Particular care must be observed with spray application in the presence of animals. Direct spraying of animals is prohibited.

**Oregon Proposal****Uses in Facilities Used for the Temporary Confinement of Animals**

A 1% solution of Virkon S is recommended to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

Application of Virkon S may occur in the presence of animals at the above listed sites, however Virkon S may not come in direct contact with animals, feed, or water. Do not allow Virkon S to pool on surfaces that may be within reach of animals. Do not allow Virkon S to come into direct contact with people. Allow Virkon S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

Handheld applications are recommended to allow precise placement on treatment site. Fogging application of Virkon S may only be conducted when no animals or people are occupying the facility.





May 2, 2003

Mr. Adam Heyward, PM #34  
Antimicrobials Branch  
US EPA  
Washington, DC 20460

Re: Amendment Adding Pest and Use Pattern  
Virkon S, EPA Reg. No. 62432-1  
Antec International Ltd.

Dear Adam:

Enclosed please find the following documents proposing an amendment to add a pest and use pattern to the Virkon S label:

- Application for Pesticide Registration (EPA Form 8570-1)
- Proposed Product Label (5 copies with proposed changes highlighted)
- Current Stamped Label

The new pest is *Rhabdovirus carpio* familiarly known as spring viremia of carp. Addition of this pest to the label was requested by APHIS officials. You may wish to speak with Samantha Bates or Dr. Nathan Birnbaum of APHIS if you have questions.

The label also proposes a use pattern, Fairs, Expositions and Exhibitions which is a variant on the existing animal health uses. Antec was recently contacted by the Oregon Department of Agriculture asking whether the current stamped label would permit use of Virkon S for disinfection of inanimate environmental surfaces at county fairs while animals were present. The approved label does not permit such uses.

Because of elevated concerns about transmission of diseases like Newcastle Disease Virus at these events, Oregon was looking for a disinfectant alternatives that could be applied several times a day as a preventive measure. Often there are not alternative animal pens and stables to which to move animals while an area is being disinfected. The purpose of the proposed instructions is to severely limit, if not eliminate, direct animal exposure when Virkon S is applied. Because the opportunity for such exposures would only be short-term and occasional, the added risk would be minimal and greatly exceeded by the benefits in disease prevention.

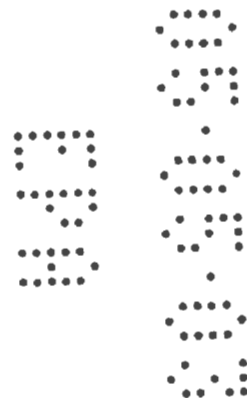
Since submission of these amendments was triggered by concerns raised by APHIS and the Oregon Department of Agriculture respectively, I ask that you give them expedited consideration.

Let me know if you have questions or need additional information. I can be contacted at [jjones@delta-ac.com](mailto:jjones@delta-ac.com) or (301) 652-5495. Thanks for your assistance.

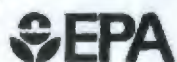
Sincerely,



T. Jeffrey Jones, Agent  
Antec International Ltd.  
Enclosures







United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number  
250999

## Application for Pesticide - Section I

1. Company/Product Number 62432-1	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Virkon S	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd. c/o Delta Analytical Corp. 7910 Woodmont Ave., Suite 1000 Bethesda, MD 20814  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____  Product Name _____	

## Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.


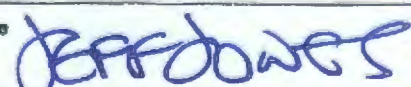
**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Amendment adding pest, Rhabdovirus carpio (spring viremia of carp (SVC) virus), and variation on existing animal health uses to permit use at fairs, exhibitions, expositions and similar events in the presence of animals.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Jeff Jones		Title Agent, Antec International Ltd.		Telephone No. (Include Area Code) 301 652 5495	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.					8. Date Application Received (Stamped)  75
2. Signature 		3. Title Agent, Antec International Ltd.			
4. Typed Name Jeff Jones		5. Date 2 May 2003			

**Master Label**

**Virkon<sup>®</sup> S**  
**BROAD SPECTRUM DISINFECTANT**

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities (OPT.)

Effective against Viruses  
(including CANINE PARVOVIRUS) • Bacteria • Fungi

For Use in Emergency Disease Control (OPT.)

For use in Cleaning and Disinfecting Institutional and Service Facilities including stores, factories, schools, hotels, offices, ships, planes, transportation terminals, supermarkets and food warehouses. (OPT.)

For Use in Emergency Response and On-site Cleanup (emergency response calls, crime scenes, traffic accidents, fires, flood, natural and other disasters) e.g. cars, trucks, ambulances, and similar emergency apparatus, tires, wheels, floors, walls, ceilings, paved surfaces; and equipment such as SCBA, coats, boots, hats, masks, gloves, axes, Jaws of Life and similar emergency equipment.(OPT.)

For Use in Greenhouses, Horticulture, and Aquaculture (OPT.)

**ACTIVE INGREDIENTS:**

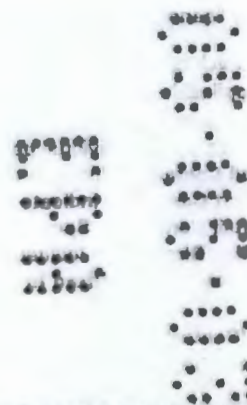
Potassium peroxymonosulfate.....	20.4%
Sodium Chloride.....	1.5%
OTHER INGREDIENTS.....	<u>78.1%</u>
TOTAL.....	100.00%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

See [Back] [Side] Panel[s] [Inside Booklet] for Additional Precautions





Front Panel Continued

**FIRST AID**

**Have the product container or label with you when calling a poison control center or doctor, or going for treatment.**

**If Swallowed:**

- Call Poison Control Center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor
- Do not give anything by mouth to an unconscious person

**If Inhaled:**

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a Poison Control Center or doctor for further treatment advice.

**If in Eyes:**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present after 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for further treatment advice.

**If on Skin:**

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center or doctor for further treatment advice.

**Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage.

\_\_\_ lbs. ( \_\_ ) Net Weight

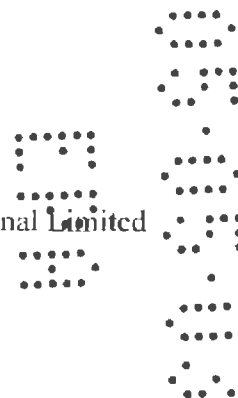
EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

Antec  
International  
LEADERS IN BIOSECURITY

Manufactured By:  
ANTEC INTERNATIONAL LTD.  
Windham Road, Chilton Industrial Estates  
Sudbury Suffolk CO10 2XD, England

Virkon<sup>®</sup> S is a registered trademark of and manufactured by Antec International Limited  
US Patent No. 4822512



[Comment: The list of claims (sites) under "EFFECTIVE AGAINST" may be placed in any order as long as each subheading and its contents remains intact.]

## EFFECTIVE AGAINST THE FOLLOWING PATHOGENS:

### ANIMAL AND ZOONOTIC PATHOGENS

#### BACTERIA

Actinobacillus pleuropneumonia  
Bordetella avium  
Bordetella bronchiseptica  
Campylobacter pyloridis  
Clostridium perfringens  
Dermatophilus congolensis  
Escherichia coli  
Fistulous withers (Poll Evil)  
Haemophilus somnus  
Klebsiella pneumoniae  
Moraxella bovis (Pink Eye)  
Mycobacterium bovis  
Mycoplasma gallisepticum  
Mycoplasma mycoides  
Pasteurella multocida  
Pseudomonas aeruginosa  
Pseudomonas mallei (Glanders)  
Pseudomonas vulgaris  
Salmonella choleraesuis  
Salmonella typhimurium  
Staphylococcus aureus  
Staphylococcus epidermidis  
Streptococcus equi (Strangles)  
Streptococcus pyogenes  
Streptococcus suis  
Taylorella equigenitalis  
Treponema hyodysenteriae

Avian Laryngotracheitis Virus  
Bovine Adenovirus Type 4  
Bovine Polyoma Virus  
Bovine Pseudocowpox Virus  
Bovine Viral Diarrhea Virus  
Calf Rotavirus  
Canine Adenovirus  
Canine Coronavirus  
Canine Parainfluenza Virus  
Canine Parvovirus  
Chicken Anemia Virus  
Coital Exanthema Virus  
Distemper Virus  
Duck Adenovirus  
Duck Enteritis Virus  
Egg Drop Syndrome Adenovirus  
Equine Infectious Anemia Virus (Swamp Fever)  
Equine Arteritis Virus  
Equine Herpes Virus (Type 1)  
Herpes Virus Equine (Type 3)  
Hog Cholera Virus  
Equine Contagious Abortion Virus  
Equine Papillomatosis Virus  
Equine Influenza Virus (Type A)  
Equine Influenza Virus (The Cough)  
Feline Calicivirus  
Feline Herpes Virus  
Feline Infectious Peritonitis Virus  
Feline Panleukopenia Virus  
Feline Parvovirus  
Feline Rhinotracheitis Virus  
Foot and Mouth Disease Virus  
Infectious Bronchitis Virus  
Infectious Bursal Disease Virus  
Infectious Canine Hepatitis Virus  
Infectious Pancreatic Necrosis Virus

#### VIRUSES

Adenovirus Pneumonia  
African Horse Sickness Virus  
African Swine Fever Virus  
Avian Influenza Virus



Infectious Salmon Anaemia Virus  
 Infective Bovine Rhinotracheitis Virus  
 Leptospira Canicola Virus  
 Maedi- Visna Virus  
 Marek's Disease Virus  
 Newcastle Disease Virus  
 PCV2 Virus (PMWS)  
 Porcine Parvovirus  
 Porcine Reproductive and Respiratory  
 Syndrome Virus (PRRS)  
 Pseudorabies Virus (Aujeszky's Disease)  
*Rhabdovirus carpio* (Spring Viremia of Carp  
 (SVC) virus)  
 Rotaviral Diarrhea Virus  
 Snakehead rhabdovirus  
 SV40 Virus  
 Swine Influenza Virus  
 Transmissible Gastroenteritis Virus (TGE)  
 Turkey Herpes Virus  
 Turkey Rhinotracheitis Virus  
 Vesicular Stomatitis Virus

## PLANT PATHOGENS

Alternaria solani  
 Botrytis cinera  
 Colletotrichum coccodes  
 Didymella bryoniae  
 Fusarium oxysporum  
 Fusarium solani  
 Penicillium oxalicum  
 Phomopsis sclerotoides  
 Pyrenochaeta lycoopersici  
 Pythium aphanidermatum  
 Rhizoctonia solani  
 Sclerotinia sclerotiorum  
 Thielaviopsis basicola  
 Verticillium dahliae

## FUNGI

Aspergillus fumigatus  
 Candida albicans  
 Fusarium moniliforme  
 Microsporum canis  
 Trichophyton spp. (Ringworm)  
 Trichophyton spp. (Mud Fever)

## EFFECTIVE AGAINST THE FOLLOWING HUMAN HEALTH PATHOGENS

Human Immuno-Deficiency Virus (HIV) Type 1 (on hard, non-porous surfaces). Streptococcus pyogenes, Campylobacter pyloridis, klebsiella pneumoniae, Escherichia coli. Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, and Candida albicans.

## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER.** Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety

glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. **Corrosive statement refers to powder only not in use solution.**

[Comment: The instructions under "DIRECTIONS FOR USE" may be placed in any order as long as they remain a continuous section on the label.]

### BROAD SPECTRUM DISINFECTANT

Virkon<sub>®</sub> S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy of the 1% solution was determined in the presence of 400 ppm AOAC hard water and 5% organic material. Virkon<sub>®</sub> S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water. Apply a 0.5% (1:200) solution for routine sanitation.

### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

### GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.
2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.
8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

This powder formula is easily diluted for use in manual or machine operations.

### Virkon<sub>®</sub> S DILUTION CHART

*Fill container with desired amount of water and add Virkon<sub>®</sub> S powder to achieve recommended solution concentration.*



<i>Quantity of Water</i>	<i>0.5% Solution</i>	<i>1% Solution</i>	<i>2% Solution</i>
<i>1 Quart</i>	<i>0.15 ounces</i>	<i>0.3 ounces</i>	<i>0.7 ounces</i>
<i>1 Gallon</i>	<i>0.65 ounces</i>	<i>1.3 ounces</i>	<i>2.7 ounces</i>
<i>10 Gallons</i>	<i>6.7 ounces</i>	<i>13.4 ounces</i>	<i>26.7 ounces</i>
<i>50 Gallons</i>	<i>33.4 ounces</i>	<i>66.8 ounces</i>	<i>133.5 ounces</i>

*Measuring cup provided.*

Solutions are stable for 7 days. Do not soak metal objects in Virkon<sub>x</sub> S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

### POULTRY [PRODUCTION] [AND RATITE PRODUCTION]

[CONTROLS: Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts) - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*. Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium* and *Mycoplasma gallisepticum*.] (OPT.)

HATCHERIES: Virkon<sub>x</sub> S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.

Virkon<sub>x</sub> S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon<sub>x</sub> S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon<sub>x</sub> S. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: Use Virkon<sub>x</sub> S at 0.5-1% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

PROCESSING PLANTS: Spray Virkon<sub>x</sub> S at 1% solution to disinfect and clean walls, ceilings and floors.

### SWINE PRODUCTION

[CONTROLS: Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine Fever and Foot

and Mouth Disease. Bacteria of Pleuropneumonia, *Treponema hyodysenteriae*, and *Clostridium perfringens*. Fungi: *Fusarium moniliforme*.] (OPT.)

Follow General Instructions to remove swine and preclean area to be treated. Virkon<sub>s</sub> S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon<sub>s</sub> S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

## EQUINE PRODUCTION

### BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

[CONTROLS: Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis. Bacterial: Clostridial Diarrhea, Fistulous Withers (Poll Evil), *Taylorella equigenitalis*, *Bordetella bronchiseptica*, *Streptococcus equi* (Strangles) and *Pseudomonas mallei* (Glanders). Fungi: Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), and *Fusarium moniliforme*.] (OPT.)

APPLICATIONS: For cleaning and disinfecting all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

### USES:

Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon<sub>s</sub> S solution. Rinse with clean water.

Blankets, Saddle Pads and Rugs: Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

Aerial Spraying to control airborne diseases: Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon<sub>s</sub> S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.

## BOVINE PRODUCTION

[CONTROLS: Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies and Foot and Mouth Disease; Bacteria of *Maraxella bovis*, *Haemophilus somnus* and *Mycobacterium bovis*; Fungi of *Fusarium moniliforme*.] (OPT.)



Follow General Instructions to remove livestock and pre-clean area to be treated. A 1% solution of Virkon<sub>®</sub> S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

## COMPANION ANIMALS

[CONTROLS: Viruses of Canine Parvovirus, Distemper, Leptospira canicola, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa; Fungi of Microsporum canis.] (OPT.)

[APPLICATIONS] A 1% solution of Virkon<sub>®</sub> S is recommended as a "one step" cleaning and disinfecting procedure for all surfaces, equipment, instruments, utensils and cages [caging systems] within [associated with] Veterinary Medical Hospitals, infectious disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon<sub>®</sub> S for long periods - 10 minutes is maximum contact time.

## GREENHOUSES AND HORTICULTURE

Virkon<sub>®</sub> S is intended to disinfect inanimate environmental surfaces, glasshouse structures, equipment, utensils, trays, containers, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

Remove all crop debris, strings and other deposits from structures, empty trays and pots. Power wash all the dust off the covering and superstructure and let dry. Using a sprayer or fogger saturate all surfaces with a 1% solution of Virkon<sub>®</sub> S. Let air dry.

Virkon<sub>®</sub> S may also be used to disinfect irrigation tanks and lines. Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon<sub>®</sub> S at 0.5-1%% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

## AQUACULTURE

Virkon<sub>®</sub> S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon<sub>®</sub> S may also be used in foot dips. Virkon<sub>®</sub> S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon<sup>®</sup> S solution followed by a water rinse.

Virkon<sup>®</sup> S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

### EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

**CONTROLS:** OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus. (OPT.)

A 1% solution of Virkon<sup>®</sup> S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

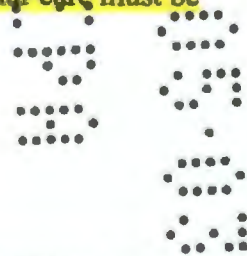
Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray Virkon<sup>®</sup> S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon<sup>®</sup> S for long periods - 10 minutes is maximum contact time.

### FAIRS, EXHIBITIONS AND EXPOSITIONS

A 1% solution of Virkon<sup>®</sup> S is recommended to clean and disinfect inanimate environmental surfaces such as pens, cages, stalls, stables, and walkways at fairs, exhibitions, expositions and similar events. Application of Virkon S may occur in the presence of animals at these sites only, and only if care is taken to avoid intentional contact with the animals. Particular care must be observed with spray applications when animals are present.





## INSTITUTIONAL AND SERVICE FACILITIES (HUMAN HEALTH)

**CONTROLS:** Human Immuno-Deficiency Virus (HIV) Type 1 (on hard, non-porous surfaces), *Streptococcus pyogenes*, *Campylobacter pyloridis*, *klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Candida albicans*. (OPT.)

With Virkon<sub>®</sub> S, only one product is needed to clean and disinfect all surfaces except acid-sensitive surfaces such as copper, brass, or aluminum. Do not use Virkon S on these acid-sensitive surfaces. Avoid splashing Virkon<sub>®</sub> S solution on textiles or carpets. Virkon<sub>®</sub> S may be used on carpeting or other textiles only if area is tested for color fastness before use and treated area vacuumed when dry.

**Cleaning and Disinfecting Non-Food Contact Surfaces:** Remove gross dirt and use 1.0% Virkon<sub>®</sub> S solution prepared according to the Dilution Chart below. Apply to surface using a mop, sponge, brushes or spray device until the surface is visibly clean. Air dry. In cases of fungal or viral contamination of non-food contact surfaces, follow these instructions substituting a 2.0% Virkon<sub>®</sub> S solution.

**Sanitizing Toilet Bowls:** After flushing, sprinkle 1 oz. Virkon<sub>®</sub> S powder around the bowl, scrub with a brush, and leave for 10 minutes. Flush.

**Cleaning and Disinfecting Manikins Used in CPR Training:** Manikins should be cleaned as soon as possible at the end of each class to avoid drying of contaminants on surfaces. Disassemble the manikin as directed by the manufacturer's instructions. Thoroughly wash all internal and external surfaces and reusable protective face shields with a brush using a 1% Virkon<sub>®</sub> S solution. Let stand for 10 minutes and rinse with potable water.

**Cleaning and Disinfecting Hard, Non-porous Surfaces Suspected of HIV Type 1 Contamination:** Cover heavy spillage of body fluids with Virkon<sub>®</sub> S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste. Prepare 2% Virkon<sub>®</sub> S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

### EMERGENCY RESPONSE AND ON-SITE CLEANUP

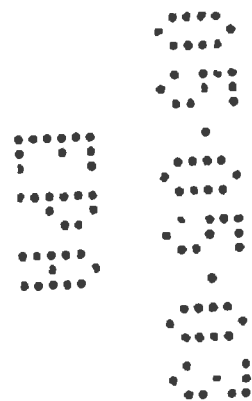
Cover heavy spillage of body fluids with Virkon<sub>®</sub> S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste.

Prepare 2% Virkon<sub>®</sub> S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

### STORAGE AND DISPOSAL

**STORAGE:** Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

**DISPOSAL:** Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals







UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

July 24, 2003

Mr. Heinz Niedermairer  
President  
Bio Safety USA.  
10220 NW 50<sup>th</sup> Street  
Sunrise, FL 33351

Subject: Petition for Tolerance Exemption  
**VIRKON®**  
Pesticide Petition Number 1F6513  
EPA Registration Number 62432-2  
Letter Date: October 31, 2002  
EPA Receipt Date: November 15, 2002

Dear Mr. Niedermaier:

The Agency has conducted a preliminary review of your petition, requesting the Agency to amend 40 CFR part § 180 by establishing an exemption from the requirement of a tolerance for residues of the active ingredient in Virkon (peroxymonosulfate) in or on all raw agriculture commodities and in processed commodities, when such residues result from the use of a 1% solution of Virkon containing a diluted end-use concentration of 0.02% peroxymonosulfate per application on food contact surfaces such as equipments, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in restaurants, food service operations, dairies, breweries, wineries, beverage and food processing plants. The sanitizer will be applied by immersion, coarse spray, or circulation technique as appropriate to the equipment or utensil. No potable water rinse is required following the use of the sanitizer.

Based on the information submitted and the Agency's review of your petition in support of the above request, the Agency is not able to act favorably at this time to your request for the following reasons:

I. Residue Chemistry Review:

1. You must provide a discussion on the chemistry of the product to explain what reactions occur when this product is used as directed.



2. You must provide a chemistry discussion on what the active components are that produce the disinfection and sanitization properties for this product. Hypochlorous acid? Hydrogen peroxide? The Agency is aware of the RED for Peroxy Compounds that states on page 17 that the use of this product produces hypochlorous acid. Is hydrogen peroxide also produced when the product is mixed with water?
3. You must submit balanced chemical equations for the chemical reactions that take place when this product is added to water.
4. You must submit the calculations used in determining the percentage of available chlorine.
5. You must submit the modeling calculations for determining residues remaining on food contact surfaces as a result of using this product, generate the actual residue data or use the FDA guidelines entitled, "Sanitizing Solutions: Chemistry Guidelines for Food Additive Petitions.

## II. Toxicology Data Requirements:

Depending upon the amount of residues found in/on the proposed food site, additional toxicology data may be required.

## III. Labeling:

Table on page 4 of the label, under the sections for: 1) Food Preparation Areas, 2) Vegetable Preparation Areas, 3) Food(Preparation in the kitchen), and 4) Bars/Restaurants, the Control column describes the use as for cleaning and disinfecting whereas the last label column for the same use sites and headed VIRKON also includes references for the sanitizer uses. The sanitizer uses for each of these sites must have separate "blocks" for sanitizer in the use table.

Please response within 75-Days from the date of this letter stating your intentions as to complying with information/data requests cited above. Include your projected time schedule for such compliance. If you are no longer interested in pursuing the proposed tolerance or exemption from tolerance, please consider voluntarily withdrawing your petition without prejudice to a future filing in accordance with 40 CFR § 180.0.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Drusilla Copeland at (703) 308-6224.

Sincerely,

Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510C)



**MASTER LABEL**

NOT REVIEWED  
In accordance with PR Notice 82-21  
Based on Draft Labeling Dated 3/4/03

**Virkon® S**  
**BROAD SPECTRUM DISINFECTANT**

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities

Effective against Viruses  
(including CANINE PARVOVIRUS) • Bacteria • Fungi

For Use in Emergency Disease Control

For use in Cleaning and Disinfecting Institutional and Service Facilities including stores, factories, schools, hotels, offices, ships, planes, transportation terminals, supermarkets and food warehouses.

For Use in Emergency Response and On-site Cleanup (emergency response calls, crime scenes, traffic accidents, fires, flood, natural and other disasters) e.g. cars, trucks, ambulances, and similar emergency apparatus, tires, wheels, floors, walls, ceilings, paved surfaces; and equipment such as SCBA, coats, boots, hats, masks, gloves, axes, Jaws of Life and similar emergency.

For Use in Greenhouses, Horticulture, and Aquaculture

**ACTIVE INGREDIENTS:**

Potassium peroxymonosulfate.....	20.4%
Sodium Chloride.....	1.5%
OTHER INGREDIENTS.....	78.1%
TOTAL.....	100.00%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

See [Back] [Side] Panel[s] [Inside Booklet] for Additional Precautions

## Front Panel Continued

**FIRST AID**

**Have the product container or label with you when calling a poison control center or doctor, or going for treatment.**

**If Swallowed:**

- Call Poison Control Center or doctor immediately for treatment advice.
- Have Person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor
- Do not give anything by mouth to an unconscious person

**If Inhaled:**

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a Poison Control Center or doctor for further treatment advice.

**If in Eyes:**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present after 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for further treatment advice.

**If on Skin:**

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center or doctor for further treatment advice.

**Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage.

**Emergency Contact Number:** 011 44 1787 377305

\_\_\_ lbs. (\_\_\_) Net Weight

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

**Antec**  
**International**  
LEADERS IN BIOSECURITY

**Manufactured By:**  
**ANTEC INTERNATIONAL LTD.**  
Windham Road, Chilton Industrial Estates  
Sudbury Suffolk C010 6XD, England

Virkon® S is a registered trademark of and manufactured by Antec International Limited  
US Patent No. 4822512



[Comment: The list of claims (sites) under "EFFECTIVE AGAINST" may be placed in any order as long as each subheading and its contents remains intact.]

## **EFFECTIVE AGAINST THE FOLLOWING ~~ANIMAL HEALTH~~ PATHOGENS:**

### **ANIMAL AND ZONOTIC PATHOGENS**

#### **BACTERIA**

Actinobacillus pleuropneumonia  
 Bacillus cereus  
 Bordetella avium  
 Bordetella bronchiseptica  
 Campylobacter pyloridis  
 Clostridium perfringens  
 Dermatophilus congolensis  
 Escherichia coli  
 Erysipelothrix rhusiopathiae  
 Fistulous withers (Poll Evil)  
 Haemophilus somnus  
 Klebsiella pneumoniae  
 Moraxella bovis (Pink Eye)  
 Mycobacterium bovis  
 Mycoplasma gallisepticum  
 Mycoplasma mycoides  
 Pasteurella multocida  
 Pseudomonas aeruginosa  
 Pseudomonas mallei (Glanders)  
 Pseudomonas vulgaris  
 Salmonella choleraesuis  
 Salmonella typhimurium  
 Staphylococcus aureus  
 Staphylococcus epidermidis  
 Streptococcus equi (Strangles)  
 Streptococcus pyogenes  
 Streptococcus suis  
 Taylorella equigenitalis  
 Treponema hyodysenteriae

#### **VIRUSES**

Adenovirus Pneumonia  
 African Horse Sickness Virus  
 African Swine Fever Virus  
 Avian Influenza Virus  
 Avian Laryngotracheitis Virus  
 Bovine Adenovirus Type 4  
 Bovine Polyoma Virus  
 Bovine Pseudocowpox Virus  
 Bovine Viral Diarrhea Virus  
 Calf Rotavirus  
 Canine Adenovirus  
 Canine Coronavirus  
 Canine Parainfluenza Virus  
 Canine Parvovirus  
 Chicken Anemia Virus  
 Coital Exanthema Virus  
 Distemper Virus  
 Duck Adenovirus  
 Duck Enteritis Virus  
 Egg Drop Syndrome Adenovirus  
 Equine Infectious Anemia Virus (Swamp Fever)  
 Equine Arteritis Virus  
 Equine Herpes Virus (Type 1)  
 Herpes Virus Equine (Type 3)  
 Hog Cholera Virus  
 Equine Contagious Abortion Virus  
 Equine Papillomatosis Virus  
 Equine Influenza Virus (Type A)  
 Equine Influenza Virus (The Cough)  
 Feline Calicivirus  
 Feline Herpes Virus  
 Feline Infectious Peritonitis Virus

Feline Panleukopenia Virus  
 Feline Parvovirus  
 Feline Rhinotracheitis Virus  
 Foot and Mouth Disease Virus  
 Infectious Bronchitis Virus  
 Infectious Bursal Disease Virus  
 Infectious Canine Hepatitis Virus  
 Infectious Pancreatic Necrosis Virus  
 Infectious Salmon Anaemia Virus  
 Infective Bovine Rhinotracheitis Virus  
 Leptospira Canicola Virus  
 Maedi- Visna Virus  
 Marek's Disease Virus  
 Newcastle Disease Virus  
 PCV2 Virus (PMWS)  
 Porcine Parvovirus  
 Porcine Reproductive and Respiratory  
 Syndrome Virus (PRRS)  
 Pseudorabies Virus (Aujeszky's Disease)  
 Rotaviral Diarrhea Virus  
 Snakehead rhabdovirus  
 SV40 Virus  
 Swine Influenza Virus  
 Transmissible Gastroenteritis Virus (TGE)  
 Turkey Herpes Virus  
 Turkey Rhinotracheitis Virus  
 Vesicular Stomatitis Virus

## FUNGI

Aspergillus fumigatus  
 Candida albicans  
 Fusarium moniliforme  
 Microsporum canis  
 Trichophyton spp. (Ringworm)  
 Trichophyton spp. (Mud Fever)

## PLANT PATHOGENS

Alternaria solani  
 Botrytis cinera  
 Colletotrichum coccodes  
 Didymella bryoniae  
 Fusarium oxysporum  
 Fusarium solani  
 Penicillium oxalicum  
 Phomopsis sclerotoides  
 Pyrenochaeta lycoopersici  
 Pythium aphanidermatum  
 Rhizoctonia solani  
 Sclerotinia sclerotiorum  
 Thielaviopsis basicola  
 Verticillium dahliae

## EFFECTIVE AGAINST THE FOLLOWING HUMAN HEALTH PATHOGENS

Human Immuno-Deficiency Virus (HIV) Type 1 (on hard non-porous surfaces), Streptococcus pyogenes, Campylobacter pyloridis, klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, and Candida albicans.



## **PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER.** Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. **Corrosive statement refers to powder only not in use solution.**

[Comment: The instructions under "DIRECTIONS FOR USE" may be placed in any order as long as they remain a continuous section on the label.]

### **BROAD SPECTRUM DISINFECTANT**

Virkon® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy of the 1% solution was determined in the presence of 400 ppm AOAC hard water and 5% organic material. Virkon® S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water. Apply a 0.5% (1:200) solution for routine sanitation.

### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

### **GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES**

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.
2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.
8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

This powder formula is easily diluted for use in manual or machine operations.



**Virkon® S DILUTION CHART**

**Fill container with desired amount of water and add Virkon® S powder to achieve recommended solution concentration.**

<b>Quantity of Water</b>	<b>0.5% Solution</b>	<b>1% Solution</b>	<b>2% Solution</b>
<b>1 Quart</b>	<b>0.15 ounces</b>	<b>0.3 ounces</b>	<b>0.7 ounces</b>
<b>1 Gallon</b>	<b>0.65 ounces</b>	<b>1.3 ounces</b>	<b>2.7 ounces</b>
<b>10 Gallons</b>	<b>6.7 ounces</b>	<b>13.4 ounces</b>	<b>26.7 ounces</b>
<b>50 Gallons</b>	<b>33.4 ounces</b>	<b>66.8 ounces</b>	<b>133.5 ounces</b>

*Measuring cup provided.*

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

### **POULTRY [PRODUCTION] [AND RATITE PRODUCTION]**

[CONTROLS: Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*. Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium* and *Mycoplasma gallisepticum*.]

**HATCHERIES:** Virkon® S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.

Virkon® S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

**BROILER/BREEDER HOUSES:** Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

**FOR AIR SANITIZING:** Use Virkon® S at 0.5-1% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

**PROCESSING PLANTS:** Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors.



## SWINE PRODUCTION

[CONTROLS: Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine Fever and Foot and Mouth Disease. Bacteria of Pleuropneumonia, Treponema hyodysenteriae, and Clostridium perfringens. Fungi: Fusarium moniliforme.]

Follow General Instructions to remove swine and preclean area to be treated. Virkon® S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

## EQUINE PRODUCTION

### BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

[CONTROLS: Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis. Bacterial: Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders). Fungi: Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), and Fusarium moniliforme.]

APPLICATIONS: For cleaning and disinfecting all surfaces, equipment, utensils and instruments in Veterinary practices , kennels, stables, catteries, etc.

#### USES:

Stables, Horse Boxes, Box Stalls, Tack ,Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution. Rinse with clean water.

Blankets, Saddle Pads and Rugs: Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

Aerial Spraying to control airborne diseases: Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon® S solution for 2-3 minutes twice daily , first thing in the morning and last thing at night. Rinse sprayers with water after use.



## BOVINE PRODUCTION

[CONTROLS: Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies and Foot and Mouth Disease; Bacteria of *Maraxella bovis*, *Haemophilus somnus* and *Mycobacterium bovis*; Fungi of *Fusarium moniliforme*.]

Follow General Instructions to remove livestock and preclean area to be treated. A 1% solution of Virkon® S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

## COMPANION ANIMALS

[CONTROLS: Viruses Canine Parvovirus, Distemper, *Leptospira canicola*, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of *Staphylococcus aureus*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*; Fungi of *Microsporum canis*.]

[APPLICATIONS] A 1% solution of Virkon® S is recommended as a "one step" cleaning and disinfecting procedure for all surfaces, equipment, instruments, utensils and cages [caging systems] within [associated with] Veterinary Medical Hospitals, infectious disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

## GREENHOUSES AND HORTICULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces, glasshouse structures, equipment, utensils, trays, containers, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

Remove all crop debris, strings and other deposits from structures, empty trays and pots. Power wash all the dust off the covering and superstructure and let dry. Using a sprayer or fogger saturate all surfaces with a 1% solution of Virkon® S. Let air dry.

Virkon® S may also be used to disinfect irrigation tanks and lines. Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon® S at 0.5-1%% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog



(wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

## AQUACULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

## EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

**CONTROLS:** OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus.

A 1% solution of Virkon® S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.



## INSTITUTIONAL AND SERVICE FACILITIES (HUMAN HEALTH)

**CONTROLS:** Human Immuno-Deficiency Virus (HIV) Type 1 (on hard non-porous surfaces), *Streptococcus pyogenes*, *Campylobacter pyloridis*, *klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Candida albicans*.

With Virkon® S, only one product is needed to clean and disinfect all surfaces except acid-sensitive surfaces such as copper, brass, or aluminum. Do not use Virkon S on these acid-sensitive surfaces. Avoid splashing Virkon® S solution on textiles or carpets. Virkon® S may be used on carpeting or other textiles only if area is tested for color fastness before use and treated area vacuumed when dry.

**Cleaning and Disinfecting Non-Food Contact Surfaces:** Remove gross dirt and use 1.0% Virkon® S solution prepared according to the Dilution Chart below. Apply to surface using a mop, sponge, brushes or spray device until the surface is visibly clean. Air dry. In cases of fungal or viral contamination of non-food contact surfaces, follow these instructions substituting a 2.0% Virkon® S solution.

**Sanitizing Toilet Bowls.** After flushing, sprinkle 1 oz. Virkon® S powder around the bowl, scrub with a brush, and leave for 10 minutes. Flush.

**Cleaning and Disinfecting Manikins Used in CPR Training:** Manikins should be cleaned as soon as possible at the end of each class to avoid drying of contaminants on surfaces. Disassemble the manikin as directed by the manufacturer's instructions. Thoroughly wash all internal and external surfaces and reusable protective face shields with a brush using a 1% Virkon® S solution. Let stand for 10 minutes and rinse with potable water.

**Cleaning and Disinfecting Hard, Non-porous Surfaces Suspected of HIV Type 1 Contamination:** Cover heavy spillage of body fluids with Virkon® S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste. Prepare 2% Virkon® S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

## EMERGENCY RESPONSE AND ON-SITE CLEANUP

Cover heavy spillage of body fluids with Virkon® S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste.

Prepare 2% Virkon® S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.



### **STORAGE AND DISPOSAL**

**STORAGE:** Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

**DISPOSAL:** Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals.



July 9, 2003

**NOT REVIEWED**  
In accordance with PB Notice 88-2.  
Based on Draft Labeling Dated

Document Processing Desk (FINAL)  
Office of Pesticide Programs (7504C)  
Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington DC 20460

Attn: Adam Heyward, PM 34  
Antimicrobial Division

**RE: Final Printed Label**

**Product name: VIRKON S – EPA Reg. # 62432-1**

**Company: Antec International Ltd.**

**EPA Letter Dated: March 6, 2003**

Dear Mr. Heyward:

On behalf of Antec International Ltd., I am submitting the final printed labeling for the product "Virkon S." This label incorporates changes per your letter of March 6, 2003.

The following documents are enclosed:

- Application for Registration of Pesticide form
- EPA letter dated March 6, 2003
- 3 copies of label

If you have any questions regarding this submission, please call me at (301) 652-5495.

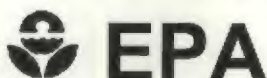
Sincerely,

Donna Leventhal  
Agent for Antec International Ltd.

Enclosures

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United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

281379

## Application for Pesticide - Section I

1. Company/Product Number <b>62432-1</b>	2. EPA Product Manager <b>Adam Heyward</b>	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>ANTEC INTERNATIONAL LTD. VIRKON S</b>	PM# <b>34</b>	
5. Name and Address of Applicant (Include ZIP Code) <b>ANTEC INTERNATIONAL LTD. c/o Delta Analytical Corp. 7910 Woodmont Ave. Suite 1000 Bethesda, MD 20814</b> <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No. _____ Product Name _____

## Section - II

<input type="checkbox"/> Amendment - Explain below <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Modification - Explain below.	X Final printed labels in response to Agency letter dated <u>03/08/03</u> <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - explain below.
Explanation: Use additional page(s) if necessary. (For section I and Section II.)	

NOT REVIEWED  
In accordance with FR Notice 88-2,  
Based on Draft Labeling Dated 3/4/03

## Section - III

1. Material this Product will be Packaged in:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted.		If "Yes," Unit Package wgt.      No. per container	If "Yes," Unit Package wgt.      No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) of Retail Container	5. Location of Label Direction <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name <b>DONNA LEVENTHAL</b>	Title <b>AGENT FOR ANTEC INTERNATIONAL LTD.</b>	Telephone No. (Include Area Code) <b>301-652-5495</b>
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any kind of knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped) 
2. Signature 	3. Title <b>AGENT FOR ANTEC INTERNATIONAL LTD.</b>	
4. Typed Name <b>DONNA LEVENTHAL</b>	5. Date <b>7/17/03</b>	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

March 6, 2003

Mr. Jeff Jones  
Delta Analytical Corp., Agent for  
*Antec International Ltd.*  
7910 Woodmont Avenue, Suite 1000  
Bethesda, MD 20814

Subject: Label Amendment  
*Virkon S*  
EPA File Symbol Number 62432-1  
Application Dated November 26, 2002

Dear Mr. Jones:

The following amendments, submitted in connection with registration under section of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable with comments listed below:

Proposed Amendment

- To add additional pests to label
- Label changes per EPA letter dated September 17, 2002

Label Comments

The following label revisions must be made:

1. The following are considered to be "Public Health" microorganisms, therefore, without acceptable efficacy data, they must be deleted from the label.

- *Bacillus subtilis*
- *Listeria monocytogenes*
- Avian Infectious Bronchitis virus



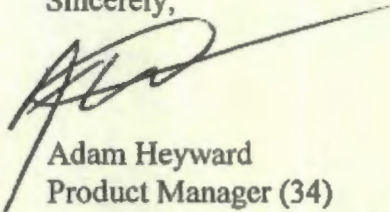
2. On page 1, delete the use in "Food Processing, including food handling and food preparation areas of restaurants and food processing plants."
3. On page 9, delete the heading "Food Processing" so that it reads "Institutional and Service Facilities (Human Health)."
4. On page 10, in the Storage and Disposal section, correct the spelling of the word "other".
5. In case of an emergency a telephone number (toll free if available) should be listed near the first aid statement.
6. Since this is a master labeling, add the word "MASTER LABEL" to the label.

**Other Comment:**

A stamped copy of the label is enclosed for your records. Submit three (3) copies of the revised final printed label before distributing or selling this product.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,



Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

July 22, 2003

Mr. Jeff Jones  
The agent for  
**Antec International Ltd.**  
c/o Delta Analytical Corp.  
7910 Woodmont Ave., Suite 1000  
Bethesda, MD 20814

Subject: Eight Month Responses to the Peroxy Compounds  
Reregistration Eligibility Decision Document (RED)  
**Virkon S**  
EPA Registration No. 62432-1  
Reregistration Application dated January 19, 2001

Dear Mr. Jones:

The product referred to above will be acceptable for reregistration under FIFRA Sec. 3 (c) 5 provided that you make the following labeling revisions. Based on the results of the data submitted as specified in the Peroxy Compounds RED, the following label revisions are required:

1. This product meets the criterion for Restricted Use Classification (RUP) based on the data that placed it in "Toxicity Category I" for primary eye irritation and primary dermal irritation categories. In lieu of classifying the subject product for RUP, the precautionary statement must be revised to read as follows:

**PRECAUTIONARY STATEMENT  
HAZARD TO HUMANS AND DOMESTIC ANIMALS  
DANGER**

**Corrosive.** Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). Wear protective clothing (long-sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet remove contaminated clothing and wash clothing before reuse.



2. The Spanish signal word "**PELIGRO**" must be added to the keep out of reach of children statement.
3. The First Aid statement must read as follows:

FIRST AID	
IF IN EYES	<ul style="list-style-type: none"> <li>- Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li> <li>- Call a poison control center or doctor for treatment advice.</li> </ul>
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> <li>- Take off contaminated clothing.</li> <li>- Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>- Call a poison control center or doctor for treatment advice</li> </ul>
IF SWALLOWED	<ul style="list-style-type: none"> <li>- Call a Poison Control Center or doctor immediately for treatment advice.</li> <li>- Have person sip a glass of water if able to swallow.</li> <li>- Do not induce vomiting unless told by a Poison Control Center or doctor.</li> <li>- Do not give anything by mouth to an unconscious person</li> </ul>
HOT LINE NUMBER	
In case of an emergency call toll free (insert 1-800-number). Have the product container or label with you when calling a poison control center or doctor or going for treatment.	
NOTE TO PHYSICIAN	
"Probable mucosal damage may contraindicate the use of gastric lavage."	

The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

4. The label claims are acceptable regarding the use of a 1% solution of the product, Virkon S, as cleaner-disinfectant against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *salmonella choleraesuis* in the presence of hard water and organic material on hard non-porous surfaces for a contact time of 10 minutes. However the label must identify the concentration of hard water or organic soil loading.



5. The label claims against *Campylobacter pylorodis* are acceptable. However, more information must be provided on the strain used in the study of *Campylobacter pylorodis*. The strain was identified only by the testing laboratory's in-house ID number ("GBL"), and the characteristics of that strain are not known. Note also that the *Campylobacter pylorodis* tested was probably *Campylobacter pylori*, and is now called *Helicobacter pylori*.
6. The label claims are not currently acceptable regarding the use of 1% solution of the product, Virkon S as a disinfectant against *Escherichia coli*, *Klebsiella pneumoniae*, *Staphylococcus epidermidis*, *Streptococcus pyogenes*, *Salmonella typhimurium* and *Candida albicans* in the presence of 400 ppm hard water on hard, non-porous surfaces for a contact time of 10 minutes. Although no growth was observed in subcultures of the carriers tested, the studies were not conducted in the presence of an organic soil load. Page 4 of the label indicates that product "efficacy was determined in the presence of hard water and organic material." Therefore, you must provide information that clarifies whether the 1989 studies or any other studies were conducted in the presence of an organic soil load against the above listed microorganisms.
7. The label include claims of effectiveness against Humanimmunodeficiency Virus (HIV), however, the data submitted did not include studies to confirm the claims of effectiveness against HIV for a contact time of minutes (or until air -dried). The label needs to clearly indicate the efficacy relates specifically to HIV type 1. In addition, the label needs to clearly indicate the efficacy relates to hard, non-porous surfaces.
8. The label claims (as supported by MRID No. 410574-10) are not currently acceptable regarding the use of a 1% solution of the product Virkon S, as a disinfectant against *Escherichia coli*, *Klebsiella pneumoniae*, *Staphylococcus epidermidis*, *Streptococcus pyogenes*, *Salmonella typhimurium*, and *Candida albicans* in the presence of 400 ppm hard water on hard, non-porous surfaces for a contact time of 10 minutes. Although no growth was observed in subcultures of the carriers tested, the studies were not conducted in the presence of an organic soil load. Page 4 of the label indicates that product "efficacy was determined in the presence of hard water and organic material." To maintain these claims, you must provide information that clarifies whether the 1989 studies or any other studies were conducted in the presence of an organic soil load against the above-listed microorganisms.

#### General Comments

The "Notice of Registration" will be issued when you submit three (3) copies of the labeling incorporating the above revision.

This letter does not constitute reregistration.

For additional labeling clarity and consistency, please refer to the enclosed EPA's Special Review and Reregistration Division review dated February 20, 2001. Submit three (3) copies of the revised labeling in accordance with the above label revisions.



If you have any questions concerning this matter, please contact me at (703) 308-6422 or Lisa McKelvin at (703) 308-7496.

Sincerely,

Adam Heyward  
Product Team (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

Enclosure(s):  
EPA SRRD Review



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

03/19/2003

**MEMORANDUM:**

**Subject:** **Virkon<sup>®</sup> S**  
EPA Reg. No. 62432-1  
Re: PRB Label Assessment

**From:** Maria Rivera Piansay, Chemist *Maria Rivera Piansay*  
Product Reregistration Branch  
Special Review and Reregistration Division (7508C)

**Through** Judy Loranger *Judy Loranger 3/31/03*  
Product Reregistration Branch  
Special Review and Reregistration Division (7508C)

**To:** Marshall Swindell  
Product Manager 33  
Antimicrobials Division (7510C)



**BACKGROUND:** Antec International, Ltd. has submitted 5 copies of draft labeling for the subject product in its 8 month response to the Peroxy Compounds RED. PRB has completed a preliminary assessment of the draft labeling. Since then, the registrant has also submitted a label for amendment to the Registration Division and that label was stamped accepted on 08/01/02. PRB has completed its preliminary assessment for product reregistration based on the stamped accepted label dated 08/01/02. In its assessment, PRB has considered the following: 1) Labeling requirements specified in the Peroxy Compounds RED; 2) Labeling specified or required in the Product Chemistry, Acute Toxicity and Efficacy Reviews; and 3) Labeling requirements as specified in 40 CFR Part 156.10 and associated labeling policy documents such as the Label Review Manual or Pesticide Regulation Notices (PRNs). In addition, PRB has made recommendations that will improve the comprehension and consistency of all product labels. This document can be accessed electronically on the Lan through the Q:Drive in Word Perfect. The path is q:\rd\user\prb\label\062432\00001.

**NOTE:** This preliminary assessment contains recommendations intended to assist Product Managers in their final review of the pesticide label. Product Managers are encouraged to use all or portions of this assessment and then apply their own knowledge of the subject product and the product's regulatory history (including comparison with existing stamped accepted labeling) to conduct a final review of the label. It is the responsibility of the PM to attain the necessary label improvements required for final product reregistration.

**Note to PM:** This product also contains the active ingredient sodium chloride addressed in the Inorganic Halides RED. No additional labeling is required per the Inorganic Halides RED.

### **SUMMARY OF FINDINGS:**

#### **I RED Risk Mitigation:**

The subject product label does not contain risk mitigation labeling requirements as specified in the Peroxy Compounds RED.

- The Environmental Hazards heading and text must be added to the label.

#### **II Technical Review Requirements:**

**Product Chemistry:** The subject product label does not contain the required labeling as specified in the product chemistry review by M. Piansay dated 03/28/01.

- The Physical or Chemical Hazards header and text must be added to the label.
- Revisions are needed to the Storage and Disposal section.

**Acute Toxicity:** The subject product label does not contain the required labeling as



specified in the acute toxicity review by M. Piansay dated 02/20/01.

- The signal word "PELIGRO" must be added to the label.
- This product meets the criterion for "Restricted Use Classification" based on data that place it in toxicity category I for eye and skin irritation. In lieu of classifying the product for restricted-use, the product manager may consider requiring alternative labeling such as face shield, goggles, safety glasses and/or gloves (to mitigate the identified hazards).
- The First Aid statements must be revised.
- The Hazards to Humans and Domestic Animals must be revised.
- Additional Note to Physician statements are recommended.

**Efficacy:** As per the efficacy review by E. Mitchell dated 02/03/03, the following revisions are required on the label:

- Identify the concentration of hard water or organic soil loading regarding use of 1% solution of the product against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Salmonella choleraesuis*.
- Delete disinfectant claims against *Escherichia coli*, *Klebsiella pneumoniae*, *Staphylococcus epidermis*, *Streptococcus pyogenes*, *Salmonella typhimurium*, and *Candida albicans* or provide information that clarifies whether the studies were conducted in the presence of an organic soil load against these microorganisms.

Note to PM: As per the efficacy review, continued approval of label claims against "*Campylobacter pyloridis*" is concurrent with submission of additional information on the strain used in the study. Furthermore, the review recommends that claims of effectiveness against HIV should be more clearly defined on the label. PRB defers these issues to RD.

### III Other Labeling Requirements:

The subject product does not contain the required labeling as specified by 40 CFR Part 156.10, PR Notices and the Label Review Manual.

- The Hotline information should be added under First Aid.
- A use restriction statement should be placed under the General Precautions and Restrictions heading.

Note to PM: PRB has no comments to the Agency letter (Adam Heyward to Mr. T. Jeffrey Jones) dated 08/01/02.

Refer to Appendix 1 for more details and to Appendix II for suggested placement information.



## **RECOMMENDATIONS:**

The subject product requires revisions to conform with the Technical Reviews and Agency label policies. Subject to final review by the Product Manager, PRB recommends that the registrant resubmit to the Product Manager, revised product labeling that addresses the deficiencies specified in this review and any other deficiencies specified by the Product Manager.

Refer to Appendix I.

**PRB Label Analysis**

Label Requirement	Acceptable	Not Acceptable	Comments/Recommendations
Restricted Use Pesticide		X	As per the acute toxicity review dated 02/20/01, this product meets the criterion for "Restricted Use Classification" based on data that place it in toxicity category I for eye and skin irritation. In lieu of classifying the product for restricted-use, the product manager may consider requiring alternative labeling such as face shield, goggles, safety glasses and/or gloves (to mitigate the identified hazards).
Product Name	X		
Company Name and Information	X		
Identification Numbers	X		
Ingredients Statement	X		
Net Contents	X		
KOROC	X		
Signal Word		X	The signal word "PELIGRO" must be added to the label.  See Appendix II for placement.
<b>Precautionary Statements</b>			
Precautionary Statements Header	X		
First Aid		X	As per the acute toxicity review and PR Notice 2001-1, the First Aid statements must be revised to read as specified below:  IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.  IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.  IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water  (Continued next page)



First Aid (continued)		X	<p>if able to swallow. Do not induce vomiting unless told to by a poison control center or a doctor. Do not give anything by mouth to an unconscious person.</p> <p>Have the product container or label with you when calling a poison control center or doctor or going for treatment.</p> <p>Hotline information that needs to be added to the label as per PR Notice 2001-1.</p> <p>"For additional information in case of emergency call toll free (Telephone Number)."</p> <p><u>Note to PM:</u> According to the acute toxicity review, since the product is classified as category IV for acute inhalation, no first aid statements are required. PRB will have no objection if the registrant wishes to retain the inhalation statements currently on the label. However, as per PR Notice 2001-1, the inhalation statements must be revised as follows:</p> <p>IF INHALED: Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.</p> <p>See Appendix II for recommended placement.</p>
Note to Physician	X		<p><u>Note to PM:</u> PRB recommends that the "Note to Physician" also include text that addresses the eye and dermal irritation concerns and should include the following information:</p> <ul style="list-style-type: none"> <li>- technical information on symptomatology,</li> <li>- use of supportive treatments to maintain life functions,</li> <li>- medicine that will counter act the specific physiological effects of the pesticide.</li> <li>- company telephone number to specific medical personnel who can provide specialized medical advice.</li> </ul>
Hazards to Humans and Domestic Animals		X	<p>As per the acute toxicity review, the HHDA statements must be modified as specified below:</p> <p>"Corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse."</p>
PPE	X		See Appendix II for recommended placement information.
User Safety Requirements	N/A		
Engineering Controls	N/A		

Engineering Controls	N/A		
User Safety Recommendations	N/A		
Environmental Hazards		X	<p>As per the RED, the following environmental hazard statement must be added to the label: "Do not discharge effluent containing these products, into lakes, streams, ponds, estuaries, oceans, or public waters unless these products are specifically identified and addressed in a NPDES permit. Do not discharge effluent containing these products to sewer systems without previously notifying the sewage plant authority. For guidance contact your State Water Board or Regional Office of the U.S. Environmental Protection Agency."</p> <p><u>Note to PM:</u> PRB defers to AD regarding the need for the text below, required on page 23 of the RED for veterinary uses:</p> <p>"This pesticide is toxic to birds, fish and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk."</p> <p>See Appendix II for placement.</p>
Physical and Chemical Hazards		X	<p>Per the product chemistry review, a PHYSICAL OR CHEMICAL HAZARDS heading must be added to the label which includes statements that address the product's oxidizing capability.</p> <p>See Appendix II for placement.</p>
Directions for Use (FIFRA Text, WPS and Storage and Disposal)			
Header "Directions for Use"	X		
Violation of Federal Law Text	X		
WPS Text	N/A		
Non- WPS Text	N/A		
Storage and Disposal		X	<p>Per the product chemistry review and the Label Review Manual, the Storage and Disposal section must be revised to read:</p> <div style="border: 1px solid black; padding: 10px; margin: 10px 0;"> <p style="text-align: center;"><b>STORAGE AND DISPOSAL</b></p> <p>Do not contaminate water, food, or feed by storage and disposal.</p> </div> <p>(Continued next page)</p>



Storage and Disposal (continued)		X	<div> <p><u>Pesticide Storage:</u> Store in a cool, dry place in tightly closed container away from children. Always replace lid after use. Do not store in metal containers.</p> <p><u>Pesticide Disposal:</u> Wastes resulting from use of this product may be disposed of on site or at approved waste disposal facility.</p> <p><u>Container Disposal:</u> Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals.</p> </div> <p><u>Note to PM:</u> The registrant should correct the spelling of "other" (otherb).</p> <p>See Appendix II for suggested placement.</p>
Directions for Use (General Instructions and Information)			
General Instructions and Information Sub-Header	N/A		
Chemigation/Prohibition (if applicable)	N/A		
Spray Drift Labeling	N/A		
General Information (non-site specific information on uses, pests, mixing and loading, tank mixing, etc....)	N/A		
General Precautions and Restrictions	X		<p><u>Note to PM:</u> PRB recommends that the statement "Do not immerse metal objects in VIRKON-S for long periods-10 minutes is maximum contact time.", currently appearing before the Storage and Disposal section should be placed under the subheading General Precautions and Restrictions.</p> <p><u>Note to PM:</u> PRB defers to AD whether the statements ("Because pH may affect both the redox potential of the reaction and the speciation of the weak hypochlorous acid reaction product, the pH of the dilution water must be specified on the labels of products containing potassium peroxydisulfate and sodium chloride salts. The optimum sanitation potential and safe use of the product occurs in the pH range of 7.2 - 7.6.") found on page 23 of the RED should be added to the label</p> <p>See Appendix II for suggested placement.</p>
Directions for Use (Application Instructions)			
Application Instructions	X		

Application Instructions	X		
Warranty Information			
Consistency with label instructions	X		
Not false and misleading	N/A		
General Comments			
None			

## Appendix II

### Suggested Presentation of Label

**Product Name**

**Ingredients.....**

**EPA Registration and Establishment Numbers**

**Company Name, Address, Phone Number**

**Net Contents**

**KEEP OUT OF REACH OF CHILDREN**

**SIGNAL WORD**

**DANGER**

**PELIGRO**

FIRST AID	
<b>IF IN EYES</b>	*Hold eye open and rinse slowly and gently with water for 15-20 minutes. *Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. *Call a poison control center or doctor for treatment advice.
<b>IF ON SKIN OR CLOTHING</b>	*Take off contaminated clothing. *Rinse skin immediately with plenty of water for 15-20 minutes. *Call a poison control center or doctor for treatment advice.



<b>IF SWALLOWED</b>	<ul style="list-style-type: none"> <li>* Call poison control center or doctor immediately for treatment advice.</li> <li>* Have person sip a glass of water if able to swallow.</li> <li>* Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>* Do not give anything by mouth to an unconscious person.</li> </ul>
<b>IF INHALED</b> (optional)	<ul style="list-style-type: none"> <li>* Move person to fresh air.</li> <li>* If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.</li> <li>* Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>HOT LINE NUMBER</b>	
<p>"In case of emergency call toll free number XXXXX."</p> <p>"Have the product container or label with you when calling a poison control center or doctor or going for treatment."</p>	
<b>NOTE TO PHYSICIAN</b>	

## **PRECAUTIONARY STATEMENTS**

### **HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**PPE**

### **ENVIRONMENTAL HAZARDS**

### **PHYSICAL OR CHEMICAL HAZARDS**

## **DIRECTIONS FOR USE**

**It is a Violation of Federal Law.....**

<b>STORAGE AND DISPOSAL</b>
---------------------------------

**General Information (non-site-specific)**

**General Precautions and Restrictions**

### **APPLICATION INSTRUCTIONS (site-specific)**

**Application Instructions**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

February 3, 2003

**MEMORANDUM:**

**Subject:** Efficacy Review for EPA Reg. No. 62432-1, "Virkon® S"  
DP Barcode: D282766  
Case No: 001751

**From:** Emily Mitchell, M.S., Team Leader *Emily Mitchell 2/4/03*  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510C)

**Through:** Benjamin Chambliss, Acting PM 36  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

**To:** Barbara Briscoe /Veronica Dutch  
Product Science Branch  
Special Review and Reregistration Division (7508C)

**Applicant:** Antec International Ltd.  
Sudbury, Suffolk, England

**Formulation From Label:**

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Potassium peroxymonosulfate.....	20.4%
Sodium Chloride.....	1.5%
<u>Inert Ingredient(s)</u> .....	<u>78.1%</u>
Total .....	100.00%



## I BACKGROUND

The product, Virkon S (EPA Reg. No. 62432-1), is an EPA-approved disinfectant (bactericide, virucide, and fungicide) for use on hard, non-porous surfaces in industrial, animal, and agricultural facilities, and institutional and food processing facilities. The product label claims that "efficacy was determined in the presence of hard water and organic material." This report documents the review of product-specific data submitted by the applicant for the 8 month response for re-registration. The data package contained efficacy data for 9 bacteria and 1 yeast. All studies were conducted at Gibraltar Biological Laboratories, Inc. located at 122 Fairfield Road, Fairfield, New Jersey 07006.

This data package contained EPA Form 8570-4 (Confidential Statement of Formula), two studies (MRID Nos. 410574-10 and 410574-11), Statements of No Data Confidentiality Claims for both studies, and a label (date stamped by EPA on October 4, 1994).

## II USE DIRECTIONS

The product is designed to be used as a broad spectrum disinfectant on hard, non-porous surfaces such as floors, walls, equipment, utensils, housing (e.g., chutes, stalls, cages), vehicles, and water-proof footwear. Directions on the last accepted label (dated August 1, 2002) provide the following information regarding preparation and use of the product as a disinfectant: **General instructions for poultry and farm premises:** Remove all animals, vehicles, enclosures, litter, feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent. Rinse with water. Saturate surfaces with a 1% solution of the product for 10 minutes. Immerse any other equipment used (ropes, forks, shovels, etc.). Ventilate areas until dried. Thoroughly scrub food contact materials with soap or detergent. Rinse with potable water before reuse. Can be used in foggers and in pressure washers. **To control airborne diseases:** Use sprayer with fine setting. Spray 1% solution 2-3 minutes twice daily. Rinse sprayers with water after use.

## III AGENCY STANDARDS FOR PROPOSED CLAIMS

### Disinfectants for Use on Hard Surfaces (Against a Broad Spectrum of Microorganisms)

The effectiveness of disinfectants for use on hard surfaces must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different batches, one of which is at least 60 days old, against *Salmonella choleraesuis* (ATCC 10708) and *Staphylococcus aureus* (ATCC 6538). To support products labeled as "general disinfectants", killing on 59 out of 60 carriers is required to provide



effectiveness at the 95% confidence level. The above Agency standards are presented in DIS/TSS-1.

Effectiveness of disinfectants against specific microorganisms other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products Test, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, but not including viruses, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products Test. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different batches. To support products labeled as "disinfectants" for specific microorganisms (other than those microorganisms named in the above test methods), killing of the specific microorganism on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least  $10^4$  microorganisms survived the carrier-drying step. These Agency standards are also presented in DIS/TSS-1.

#### Supplemental Claims

An antimicrobial agent identified as a "one-step" cleaner-disinfectant, cleaner-sanitizer, or one intended to be effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. These Agency standards are presented in DIS/TSS-2.

The hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish disinfectant efficacy in hard water, all microorganisms (bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level. These Agency standards are also presented in DIS/TSS-2.

#### IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

**1. MRID 410574-10 "EPA Supplemental Registration of Virkon S Disinfectant, AOAC Use Dilution Test", by Daniel L. Prince. Study conducted at Gibraltar Biological Laboratories, Inc. Study completion date - February 16, 1989.**

This study was conducted against bacteria *Escherichia coli* (GBL=642), *Klebsiella pneumoniae* (GBL=132), *Staphylococcus epidermidis* (GBL=6), *Campylobacter pyloridis* (GBL=775), *Streptococcus pyogenes* (GBL=7), and *Salmonella typhimurium* (GBL=106), and yeast *Candida albicans* (GBL=648). The origin/nature of each of these strains was not specified. Two lots (Lot Nos. 01809160 and 02809160) of the product, Virkon S Powder, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 14<sup>th</sup> Edition, 1984. A use solution was made by diluting 5 grams of powder with 500 mL of 400 ppm



AOAC hard water (titration results not provided), resulting in a 1% solution. Ten (10) stainless steel penicylinders carriers were tested per each product lot against each test organism. *Campylobacter pyloridis* was the only organism tested in the presence of an organic soil load (5% serum). The carriers were immersed in 20 mL of 48-hour old cultures of each organism for 15 minutes. The carriers then were dried for 40 minutes at  $35\pm 1^{\circ}\text{C}$ . The contaminated penicylinders were allowed to remain in contact with the use solution for 10 minutes at  $20\text{-}25^{\circ}\text{C}$ . The recovery broth was 10 mL of Letheen Broth (Letheen Broth with 5% serum for *Campylobacter pyloridis*). The subcultures were incubated for 48 hours at  $35\pm 1^{\circ}\text{C}$ , and then observed for typical growth. Controls included population verification, neutralization verification, and viability.

**2. MRID 410574-11 "Primary Registration, AOAC Use-Dilution on Virkon S Powder", by Daniel L. Prince. Gibraltar Biological Laboratories, Inc. Study completion date - January 26, 1989.**

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442), *Staphylococcus aureus* (ATCC 6538), and *Salmonella choleraesuis* (ATCC 10708) in the presence of a 5% organic soil load (calf serum). Three lots (Lot Nos. 01809160, 02809160 and 03809160) of the product, Virkon S Powder, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 14<sup>th</sup> Edition, 1984. All three product lots were at least 60 days old at the time of testing. A use solution was made by diluting the product 1% in 400 ppm AOAC hard water (titration results not provided). Sixty (60) stainless steel penicylinders carriers were tested per each product lot against each test organism. The carriers were immersed in 20 mL of 48-hour old cultures of each organism for 15 minutes. The carriers then were dried for 40 minutes at  $35\pm 1^{\circ}\text{C}$ . The contaminated penicylinders were immersed in 10 mL of use solution. The carriers were allowed to remain in contact with the product for 10 minutes at  $20^{\circ}\text{C}$  (shaken three times each). After exposure, the carriers were placed in 10 mL of Letheen Broth containing Lecithin and Tween 80. The subcultures were incubated for 48 hours at  $35\pm 1^{\circ}\text{C}$ , and observed for typical growth. Controls included population verification, neutralization verification, and viability.

## V RESULTS

Note: The study reports are not completely legible; the MRIDs are labeled "best available copy." PSB has made every effort to transcribe the information accurately.

MRID Number	Organism	No +/Total No. Tested			Viability (CFU/carrier)
		Lot No. 01809160	Lot No. 02809160	Lot No. 03809160	
410574-10	<i>Escherichia coli</i>	0/10	0/10	—	not legible
	<i>Klebsiella pneumoniae</i>	0/10	0/10	—	$2.9 \times 10^5$
	<i>Staphylococcus epidermidis</i>	0/10	0/10	—	$9.3 \times 10^4$
	<i>Campylobacter pyloridis</i>	0/10	0/10	—	not legible
	<i>Streptococcus pyogenes</i>	0/10	0/10	—	$4.1 \times 10^4$
	<i>Salmonella typhimurium</i>	0/10	0/10	—	not legible
	<i>Candida albicans</i>	0/10	0/10	—	$3.7 \times 10^4$
410574-11	<i>Pseudomonas aeruginosa</i>	0/60	0/60	0/60	$1.5 \times 10^6$ $1.8 \times 10^6$ $3.7 \times 10^5$
	<i>Staphylococcus aureus</i>	0/60*	0/60	0/60	$7.2 \times 10^4$ $1.3 \times 10^6$
	<i>Salmonella choleraesuis</i>	0/60*	0/60	0/60	not legible $1.6 \times 10^6$ $4.2 \times 10^5$ $1.6 \times 10^6$

\* The Lot Number in the Results Table in the MRID was identified as Lot No. 01809106. PSB assumes that this is a typographical error.

## VI CONCLUSIONS

1. The submitted efficacy data (MRID No. 410574-11) support the use of a 1% solution of the product, Virkon S, as a disinfectant with bactericidal activity when tested against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Salmonella choleraesuis* in the presence of a 5% organic soil load (calf serum) and 400 ppm hard water on hard, non-porous surfaces for a contact time of 10 minutes. No growth was observed in the subcultures of the carriers tested against three lots of the product. The dried carrier counts (where the reported data were legible) were at least  $10^4$  CFU/carrier. Controls behaved as expected. Neutralization verification testing showed positive growth of the organisms.



2. The submitted efficacy data (MRID No. 410574-10) support the use of a 1% solution of the product, Virkon S, as a disinfectant when tested against *Escherichia coli*, *Klebsiella pneumoniae*, *Staphylococcus epidermidis*, *Campylobacter pyloridis*, *Streptococcus pyogenes*, *Salmonella typhimurium*, and *Candida albicans* in the presence of 400 ppm hard water on hard, non-porous surfaces for a contact time of 10 minutes. No growth was observed in the subcultures of the carriers tested against two lots of the product. The dried carrier counts (where the reported data were legible) were at least  $10^4$  CFU/carrier. Controls behaved as expected. Neutralization verification testing showed positive growth of the organisms.

Note: Only *Campylobacter pyloridis* was tested in the presence of an organic soil load (5% serum).

## VII RECOMMENDATIONS

1. The label claims (as supported by MRID No. 410574-11) are acceptable regarding the use of a 1% solution of the product, Virkon S, as a cleaner-disinfectant against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Salmonella choleraesuis* "in the presence of hard water and organic material" on hard, non-porous surfaces for a contact time of 10 minutes.

Note: The label should identify the concentration of hard water or organic soil loading.

2. The label claims (as supported by MRID No. 410574-10) against "*Campylobacter pyloridis*" are acceptable; testing of this organism was performed "in the presence of hard water and organic material." Prior to continuing approval of label claims for "*Campylobacter pyloridis*," The registrant should provide more information on the strain used in the study. The strain was identified only by the testing laboratory's in-house identification number ("GBL"), and the characteristics of that strain are not known. Note also that the "*Campylobacter pyloridis*" tested was probably *Campylobacter pylori*, and is now called *Helicobacter pylori*.

3. The label claims (as supported by MRID No. 410574-10) are not currently acceptable regarding the use of a 1% solution of the product, Virkon S, as a disinfectant against *Escherichia coli*, *Klebsiella pneumoniae*, *Staphylococcus epidermidis*, *Streptococcus pyogenes*, *Salmonella typhimurium*, and *Candida albicans* in the presence of 400 ppm hard water on hard, non-porous surfaces for a contact time of 10 minutes. Although no growth was observed in subcultures of the carriers tested, the studies were not conducted in the presence of an organic soil load. Page 4 of the label indicates that product "efficacy was determined in the presence of hard water and organic material". Prior to continuing approval of the product label, the registrant should provide information that clarifies whether the 1989 studies or any other studies were conducted in the presence of an organic soil load against the above-listed microorganisms.

4. The label includes claims of effectiveness against Human Immunodeficiency Virus (HIV); however, the data package did not include studies to confirm these claims. PSB reviewed data supporting claims of effectiveness against HIV in August 2002 [see D282057; MRID No. 456371-01]. Prior to continuing approval of the product label, the PM may wish to request that the applicant revise the HIV claims on the product label so that the claims are more clear.



3-26-01  
Lindsay/CD  
Bm



March 22, 2001

Ms. Veronica Dutch  
Product Reregistration Branch, SRRD  
US EPA  
Washington, DC 20460

Subject: EPA Reg. No. 62432-1; Telephone Conversations with Maria Piansay

Dear Ms. Dutch:

Following up on recent telephone conversations with Maria Piansay, I am submitting the following documents related to the registration of Virkon S (EPA Reg. No. 62432-1):

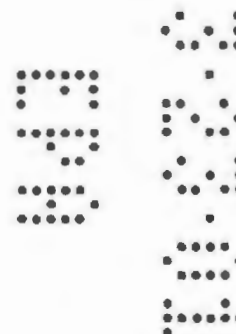
- Revised Confidential Statement of Formula; EPA Form 8570-4
- Revised Product Label

Let me know if you have any questions regarding this submission or if I need to supply additional information.

Sincerely,



T. Jeffrey Jones, Agent  
Antec International Ltd.  
Enclosures



**VIRKON-S®**  
**BROAD SPECTRUM DISINFECTANT**

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities

**ACTIVE INGREDIENTS:**

Potassium peroxymonosulfate.....	21.42%
Sodium Chloride.....	1.50%
INERT INGREDIENTS.....	<u>77.08%</u>
TOTAL.....	100.00%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

See Back [Side] Panel[s] for Additional Precautions

\_\_\_ lbs. (\_\_\_) Net Weight

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

**ANTEC INTERNATIONAL LTD.**  
Windham Road, Chilton Industrial Estates  
Sudbury Suffolk C010 6XD, England  
Tel: (1787) 77305 Telex: 987495 Fax: (1787) 310846

VIRKON S is a registered trademark of and manufactured by Antec International Limited  
US Patent No. 4822512

843

10.02.0



# EFFECTIVE AGAINST:

## EQUINE BACTERIA

Clostridium perfringens

Fistulous withera (Poll Evil)

Taylorella equigenitalis

Streptococcus equi (Strangles)

Pseudomonas mallei

(Glanders)

Bordetella bronchiseptica

## EQUINE VIRUSES

African Horse Sickness

African Viral Arteritis

(Pink Eye)

Coital Exanthema

Myeloencephalopathy

Rhinopneumonitis

Equine Infectious Anemia

(Swamp Fever)

Equine papillomatosis

Equine Contagious Abortion

Adenovirus Pneumonia

Equine Influenza (The Cough)

## EQUINE FUNGI

Trichophyton spp. (Ringworm)

Trichophyton spp.

(Mud Fever)

Fusarium moniliforme

## BOVINE BACTERIA

Moraxella bovis

Mycobacterium bovis

Haemophilus somnus

## BOVINE VIRUSES

Calf rotavirus

Infective Bovine

Rhinotracheitis

Bovine Adenovirus Type 4

Pseudorabies

Foot & Mouth Disease

## BOVINE FUNGI

Fusarium moniliforme

## POULTRY BACTERIA

Streptococcus pyogenes

Campylobacter pyloridis

Klebsiella pneumoniae

Escherichia coli

Salmonella typhimurium

Salmonella choleae

Pseudomonas aeruginosa

Staphylococcus aureus

Staphylococcus epidermidis

Mycoplasma gallisepticum

Clostridium perfringens

Bordetella avium

## POULTRY VIRUSES

Newcastle Disease

Infectious Bronchitis

Infectious Bursal Disease

Avian Laryngotracheitis

Avian Influenza

Marek's Disease

Egg Drop Syndrome

Adenovirus

Turkey Herpes Virus

Duck Herpes Virus

Duck Viral Enteritis

## POULTRY FUNGI

Aspergillus flavus

Aspergillus fumigatus

Candida albicans

## SWINE BACTERIA

Bordetella bronchiseptica

Pasteurella multocida

Actinobacillus

pleuropneumonia

Treponema hyodysenteria

Clostridium perfringens

## SWINE VIRUSES

Hog Cholera

Swine Influenza

Porcine parvovirus

Rotaviral diarrhea

Vesicular stomatitis

Pseudorabies

Porcine Reproductive and

Respiratory Syndrome

(PRRS)

African Swine Fever

Foot and Mouth Disease

## SWINE FUNGI

Fusarium moniliforme

## COMPANION ANIMALS

### BACTERIA

Streptococcus aureus

Streptococcus pyogenes

Klebsiella pneumoniae

Pseudomonas aeruginosa

### VIRUSES

Canine Parvovirus

Distemper

Leptospira canicola

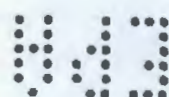
Feline parvovirus

Feline herpes

Feline calicivirus

### FUNGI

Microsporum canis





**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
DANGER**

Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive statement refers to powder only not in use solution.

**FIRST AID**

**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention if irritation persists.

**IF INHALED:** If symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

**IF SWALLOWED:** Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

**NOTICE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

**BROAD SPECTRUM DISINFECTANT**

VIRKON-S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material. *VIRKON-S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.*

**DIRECTIONS FOR USE**

Federal law prohibits use of this product in a manner inconsistent with its labeling

This powder formula is easily diluted for use in manual or machine operations.

**VIRKON-S DILUTION CHART**

*Fill container with desired amount of water and add VIRKON-S powder to achieve recommended solution concentration.*

Quantity of Water	Amount of Powder for 1% Solution	Amount of Powder for 2% Solution
1 Quart	0.3 ounces	0.7 ounces
1 Gallon	1.3 ounces	2.7 ounces
10 Gallons	13.4 ounces	26.7 ounces
50 Gallons	66.8 ounces	133.5 ounces

1.3 oz. measuring scoop is provided.





**Add [1.3 oz. (1 scoop) of VIRKON-S] [the contents of one VIRKON-S packet] to one gallon of warm water. Solutions are stable for 7 days. Do not soak metal objects for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.**

### POULTRY [AND RATITE PRODUCTION]

**CONTROLS:** Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*. Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium* and *Mycoplasma gallisepticum*.

**HATCHERIES:** VIRKON-S at 1% solution *can be used* for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). VIRKON-S at 1-2% solution is recommended for use in fogging (wet misting) operations as a *supplemental measure*, either *before or after* regular cleaning and *disinfecting* procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

**BROILER/BREEDER HOUSES:** *Remove chickens [birds], feed, and water troughs, then remove manure and litter. Spray floors and walls with VIRKON-S at 1% solution.* Thoroughly wash waterers and feeders with a 1% solution of VIRKON-S (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). *After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.*

**FOR AIR SANITIZING:** Use VIRKON-S at 1-2% solution, *and fog until* surfaces are moist. Allow at least 2 hours before entering *treated area. Rinse foggers and sprayers with water following use.*

**PROCESSING PLANTS:** *Spray VIRKON-S at 1% solution to disinfect and clean walls, ceilings and floors.*

### SWINE [PRODUCTION]

**CONTROLS:** Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine Fever and Foot and Mouth Disease. Bacteria of *Pleuropneumonia*, *Treponema hyodysenteriae*, and *Clostridium perfringens*. Fungi: *Fusarium moniliforme*.





VIRKON-S *at 1% solution* is recommended for *cleaning and disinfecting* farrowing units, nurseries, finisher houses and processing plants (use a 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus.)

VIRKON-S *at 1-2% solution* is recommended for use in fogging (wet misting) operations or as a *supplemental measure* either *before or after* regular cleaning and *disinfecting* procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. *Rinse foggers and sprayers with water following use.*

## EQUINE [PRODUCTION]

### BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

#### CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis. Bacterial: Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders). Fungi: Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), and Fusarium moniliforme.

APPLICATIONS: For cleaning and *disinfecting* all surfaces, equipment, utensils and instruments in Veterinary practices [, kennels, stables, catteries, etc].

#### USES:

~~Topical Use On Animal: Shampoo infected area with a 1% solution of VIRKON-S using a clean sponge. Rinse with clean water. Apply three times a day. Repeat as necessary.~~

Stables, [Horse Boxes, ][Box ]Stalls, Tack ,[Equipment,] and Feed Rooms: Thoroughly *clean and dry* [dry clean] *surfaces*, then wash the area manually or with pressure washer with a 1% VIRKON-S solution. Rinse with clean water.

Blankets, [Saddle Pads] [and] Rugs: Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

Aerial Spraying to control airborne diseases: *Use a hand [or knapsack] sprayer with fine setting*, or an *automatic* spraying system. *Spray a 1% VIRKON-S solution* for 2-3 minutes twice daily [, first thing in the morning and last thing at night]. *Rinse sprayers with water after use.*

## BOVINE [PRODUCTION]

CONTROLS: Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies; Bacteria of Maraxella bovis, Haemophilus somnus and Mycobacterium bovis; Fungi of Fusarium moniliforme.



**A 1% solution of VIRKON-S** is recommended *to clean and disinfect* areas associated with bovine housing [stabling], hospital [quarantine] pens and feedlot facilities.

#### COMPANION ANIMALS

**CONTROLS:** Viruses Canine Parvovirus, Distemper, *Leptospira canicola*, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of *Staphylococcus aureus*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*; Fungi of *Microsporum canis*.

[APPLICATIONS:] **A 1% solution of VIRKON-S** is recommended as a "one step" cleaning and *disinfecting* procedure for all surfaces, equipment, instruments, utensils and *cages* [caging systems] within [associated with] [Veterinary Medical Hospitals,] [infections disease wards,] [quarantine areas,] [Humane Society facilities,] [laboratory animal quarters,] grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in VIRKON-S for long periods - 10 minutes is maximum contact time.

#### STORAGE AND DISPOSAL

**STORAGE:** Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

**DISPOSAL:** Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals

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70.52.5



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

February 20, 2001

MEMORANDUM:

Subject: EPA Reg. No.: 62432-1/Virkon S  
DP Barcodes: D272689  
Case No.: 4072

From: Maria Rivera Piansay, Chemist  
Product Reregistration Branch  
Special Review and Reregistration Division (7508C)

*Maria Rivera Piansay* 02/26/01  
*MRP*

To: Veronica Dutch, CRM  
Product Reregistration Branch  
Special Review and Reregistration Division (7508C)

Applicant: Antec International, Ltd.  
Chilton Industrial Estate  
Sudbury, Suffolk CO10 6XD  
England

FORMULATION FROM EPA Reg. No. 62432-1 LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Potassium peroxymonosulfate .....	20.4%
Sodium Chloride .....	1.5%
<u>Inert Ingredient(s):</u> .....	78.1%
Total:	100.0%



## BACKGROUND:

In the 8 month response to the Peroxy Compounds RED, the registrant submitted acute oral, acute dermal, acute inhalation, primary eye irritation, primary skin irritation, and skin sensitization studies in support of the reregistration of EPA Reg. No. 62432-1. The MRID numbers are as follows: 410574-02 (81-1), 410574-03 (81-2), 410574-04 (81-3), 410574-05 (81-4), 410574-07 (81-5) and 410574-09 (81-6). The studies were conducted by Biosearch Incorporated and the test material used in the studies was Virkon-S, EPA Reg. 62432-1.

The subject product is listed in the "No Batch" table of the Peroxy Compounds RED.

## RECOMMENDATIONS:

- The submitted studies on acute oral, acute dermal, and acute inhalation toxicities are acceptable to support this product.
- The primary eye and primary skin irritation studies show that the product is a severe irritant, therefore the studies are "Self-validated" and the product is placed in toxicity category I for primary eye and skin irritation.
- The skin sensitization study is not acceptable because the results of the screening test were not included. The Agency is not able to confirm that the concentration tested (5 % w/v) was the highest concentration that would evoke mild to moderate irritation. However, due to the primary skin irritation study that shows that the product is corrosive to the skin (category I), PRB/SRRD will waive the skin sensitization requirement for this product and the product will be classified as a non-sensitizer.

The acute toxicity profile for EPA Reg. No. 62432-1 is currently:

Acute Oral	III	Acceptable
Acute Dermal	III	Acceptable
Acute Inhalation	IV	Acceptable
Primary Eye	I	Self-validated
Primary Dermal	I	Self-validated
Skin Sensitization	Not a sensitizer	Waived

**LABELING:**

**ID #: 062432-00001 VIRKON S**

**RESTRICTED USE CLASSIFICATION RECOMMENDED**

Due to eye irritation, dermal irritation toxicity categories.

The PM Team should decide if restricted use classification is necessary or if alternative labeling will allay the requirement for restricted use classification.

**SIGNAL WORD: DANGER PELIGRO**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS:**

Corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Wear coveralls over long-sleeved shirt and long pants, socks and chemical resistant footwear, goggles or face shield and chemical resistant gloves\* (such as rubber or waterproof, selection Category A). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

**FIRST AID:**

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.



NOTE TO PHYSICIAN: The following "Note to Physician" statement is required for the subject product:

*Probable mucosal damage may contraindicate the use of gastric lavage.*

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Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician" which addresses the category I eye and skin irritation. The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

\*If chemical resistance Category A (rubber or waterproof) gloves are not appropriate for this product, the registrant should indicate a specific glove category from the EPA chemical resistant glove selection that will provide adequate protection.

## DATA REVIEW FOR ACUTE ORAL TOXICITY (§81-1, 870.1100)

**Product Manager:** Adam Heyward, 34  
**MRID No.:** 410574-02

**Reviewer:** Maria Rivera Piansay  
**Study Completion Date:** 01/24/89  
**Report No.:** 88-6437A

**Testing Facility:** Biosearch Incorporated  
**Author:** D. Gabriel

**Quality Assurance (40 CFR §160.12):** included  
**Test Material:** Virkon-S, EPA Reg. No. 62432-1, white, free-flowing powder

**Species:** Sprague-Dawley rat  
**Age:** not reported  
**Weight:** 200-300 g  
**Source:** Buckshire Corp.

### Conclusion:

1. LD<sub>50</sub>: males: 1700 mg/kg; females: 1160 mg/kg; combined: 1480 mg/kg
2. Tox. Category: III                      Classification: Acceptable

**Procedure (Deviations from §81-1):** none

### Results:

Dosage (mg/kg)	Number Deaths/Number Tested		
	Males	Females	Combined
500	0/5	0/5	0/10
1000	0/5	2/5	2/10
1500	1/5	3/5	4/10
1780	2/5	---	---
2000	5/5	5/5	10/10
2500	5/5	5/5	10/10

### Observations:

All male mortalities occurred on Day 1 post exposure to 1500 and 1780 mg/kg dose level. All male deaths occurred within 24 hours of exposure to 2000 and 2500 mg/kg of the test substance. Except for ruffled fur and lethargy, all male animals appeared normal at 500 and 1000 mg/kg. Pre-death signs in the males included a normal appearance followed by comatose appearance and lethargy.



Except for appearing ruffled, no other abnormal signs were noted in the female animals dosed with 500 mg/kg of the test substance. 2/5 females died 4 hours after exposure to 1000 mg/kg of the test material. The survivors appeared ruffled Day 1 through Day 3 but appeared normal through study termination. 3/5 females died 4 hours after exposure to 1500 mg/kg test substance. The two survivors appeared ruffled Day 1 to Day 3 and appeared normal through the rest of the study period. Female mortalities at 2000 and 2500 mg/kg occurred within 24 hours of test substance administration.

All survivors gained weight throughout the study period.

#### **Gross Necropsy:**

Gross necropsy findings at terminal sacrifice revealed no abnormalities.

Gross necropsy of the male decedents at 1500, 1780, 2000 and 2500 mg/kg revealed dark nasal staining, dark liquid in the stomach and lower gastrointestinal tract, dark and irritated stomach lining, pale lungs.

Gross necropsy of the females that died at 1000, 1500, 2000 and 2500 mg/kg dose levels revealed irritation of the stomach lining and dark liquid in the lower gastrointestinal tract, injected vessels in the lower gastrointestinal tract, dark discoloration of the tissue lining of the stomach, and pale lungs.

# DATA REVIEW FOR ACUTE DERMAL TOXICITY (§81-2, 870.1200)

**Product Manager:** Adam Heyward, 34  
**MRID No.:** 410574-03

**Reviewer:** Maria Rivera Piansay  
**Study Completion Date:** 12/28/88  
**Report No.:** 88-6437A

**Testing Laboratory:** Biosearch Incorporated  
**Author:** D. Gabriel  
**Quality Assurance (40 CFR § 160.12):** included

**Test Material:** Virkon-S, EPA Reg. No. 62432-1, white, free-flowing powder  
**Species:** New Zealand white rabbit  
**Age:** not reported  
**Weight:** 2.0-3.0 kg  
**Source:** Buckshire Corp.

## Summary:

1. **LD<sub>50</sub> (mg/kg):** >2000 mg/kg

2. **Tox. Category:** III

**Classification:** Acceptable

**Procedure (Deviations From §81-2):** none

## Results:

### Reported Mortality

DOSAGE (mg/kg)	(number deaths/number tested)		
	Males	Females	Combined
2000	0/5	0/5	0/10

## Observations:

No mortalities occurred. Necrotic skin and slight to moderate edema were noted in all animals 24 hours following exposure. At Day 7, peeling and necrotic skin and slight edema were noted in all males while females exhibited peeling necrotic skin, denuded skin and slight edema. By Day 14, 4/5 males exhibited peeling necrotic skin, denuded skin and very slight to slight edema and 1/5 males exhibited well-defined erythema, denuded skin and very slight edema. By Day 14, 3/5 females had peeling necrotic skin, denude skin and slight edema and 2/5 females had peeling necrotic skin and slight edema. 1/5 female also had soft stool at Day 14.



### **Gross Necropsy:**

Gross necropsy of the males revealed gas in the small intestines, signs of diarrhea and no formed feces in one animal while signs of coccidiosis was noted in another animal. No abnormalities were observed in the 3/5 male animals.

Of the 5/5 female animals necropsied at the end of the study period, signs of coccidiosis were noted in 1/5 animals, gas and clear fluid throughout the gastrointestinal tract were noted in 1/5 animals, pitted kidneys and signs of diarrhea were noted in 1/5 animals. One animal showed no signs of abnormalities.

## DATA REVIEW FOR ACUTE INHALATION TOXICITY (§81-3, 870.1300)

**Product Manager:** Adam Heyward, 34  
**MRID No.:** 410574-04

**Reviewer:** Maria Rivera Piansay  
**Study Completion Date:** 12/19/88  
**Report No.:** 88-6437A

**Testing Laboratory:** Biosearch Incorporated  
**Author:** R.J. Herschman

**Quality Assurance (40 CFR §160.12):** included

**Test Material:** Virkon-S, EPA Reg. No. 62432-1, white, free-flowing powder  
**Species:** Prague-Dawley rat  
**Weight:** 204-276 g  
**Age:** not reported  
**Source:** Buckshire Corporation

### Summary:

1. **LC<sub>50</sub>:** >6.147 mg/L
2. **Tox. Category:** IV
3. **MMAD:** ave. 1.30 ± 0.05 µm
4. **GSD:** not reported
5. **Classification:** Acceptable

**Procedure (Deviations From §81-4):** One hundred minutes to the 4-hour exposure, the compressor overheated. The exposure was stopped and the chamber was depressurized and the compressor was allowed to cool. Exposure was resumed for an additional 17 minutes for a total exposure of 242 minutes. This deviation is not expected to affect the integrity of the study.

### Results:

#### Reported Mortality

Exposure Concentration (mg/L)	Number Deaths/Number Tested		
	Males	Females	Combined
6.147	0/5	0/5	0/10

Chamber Environment	Dose Level (mg/L)
	6.147
Chamber Volume (L)	230
Airflow (Lpm)	10
Temperature (°C)	21 ± 1°C
Relative Humidity (%)	83



**Clinical Observations:**

No mortalities occurred during the study. All animals appeared normal after the 4-hour exposure period.

Except for one female which lost weight on Day 14, all animals gained weight throughout the study period.

**Gross Necropsy Findings:**

Gross necropsy revealed no observable abnormalities.

**DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)**

**Product Manager:** Adam Heyward, 34  
**MRID No.:** 410574-05

**Reviewer:** Maria Rivera Piansay  
**Study Termination Date:** 11/15/88  
**Report No.:** 88-6437A

**Testing Laboratory:** Biosearch Incorporated  
**Author:** G.E. Moore  
**Quality Assurance (40 CFR §160.12):** included

**Test Material:** Virkon-S, EPA Reg. No. 62432-1, white, free-flowing powder  
**Dosage:** 0.08 g  
**Species:** New Zealand white rabbit  
**Age:** not reported  
**Weight:** not reported  
**Source:** Buckshire Corporation

**Summary:**

**Toxicity Category:** I

**Classification:** Self-validated

**Procedure (Deviations From §81-4):** none

**Results:**

Testing was terminated on Day 1 due to severe irritation.



**DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)**

**Product Manager:** Adam Heyward, 34  
**MRID No.:** 410574-07

**Reviewer:** Maria Rivera Piansay  
**Study Completion Date:** 12/13/88  
**Report No.:** 88-6437A

**Testing Laboratory:** Biosearch, Inc.  
**Author:** D. Gabriel

**Quality Assurance (40 CFR §160.12):** included

**Test Material:** Virkon-S, EPA Reg. No. 62432-1, white, free-flowing powder

**Dosage:** 0.5 g

**Species:** New Zealand albino rabbit

**Age:** not reported

**Sex:** not reported

**Weight:** not reported

**Source:** Buckshire Corp.

**Summary:**

**1. Toxicity Category:** I

**2. Classification:** Self-validated

# ACUTE TOX ONE-LINER

1. PC CODES: 063604, 013905
2. CURRENT DATE: February 20, 2001
3. TEST MATERIAL: Virkon-S, EPA Reg. No. 62432-1, white, free-flowing powder

Study/Species/ Lab/Study#/Date	MRID #	Results	Tox. Cat.	Core Grade
acute oral toxicity/rat/Biosearch Inc/88- 6437A/01/24/89	410574- 02	LD <sub>50</sub> : 1480 mg/kg	III	A
acute dermal toxicity/rat/Biosearch Inc/88- 6437A/12/28/88	410574- 03	LD <sub>50</sub> : > 2000 mg/kg	III	A
acute inhalation/rat/Biosearch Inc/88-6437A/12/19/88	410574- 04	LC <sub>50</sub> : > 6.147 mg/L	IV	A
primary eye irritation/rabbit/Biosearch Inc./88-6437A/11/15/88	410574- 05	Corrosive.	I	V
primary skin irritation/Biosearch Inc/88- 6437A/12/13/88	410574- 07	Corrosive.	I	V

## Core Grade Key:

- A = Acceptable
- S = Supplementary (upgradeable)
- U = Unacceptable
- V = self-Validated



DATE OUT: 28/MAR/01

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Manufacturing Use [ ], End Use Product [x]

BARCODE No.: D272683 EPA RECEIVED DATE: 01/31/01 Reg./File Symbol No.: 62432-1

PRODUCT NAME: Virkon S

MRID numbers: 420924-01, 411083-00, -01, -02, 413821-00, -01, 410574-00, -01, 412597-01

COMPANY NAME: Antec International, Ltd Action Code: 675

FROM: Maria Rivera Piansay, Chemist  
Product Chemistry Team  
PRB/SRRD (7508C)

*Maria Rivera Piansay*  
03/28/01

TO: Veronica Dutch, CRM  
Product Reregistration Branch  
Special Review and Reregistration Division (7508C)

#### INTRODUCTION:

Antec International, Ltd. submitted the MRID numbers 420924-01, 411083-00, -01, -02, 413821-00, -01, 410574-00, -01, and 412597-01, a basic formulation CSF dated 03/22/01, and a draft label EPA received 03/23/01, in response to a previous product chemistry review by SRRD/PRB (dated 11/30/00, Barcode number D270554) wherein Series 61, 62 and 63 product chemistry requirements were cited as data gaps for the reregistration of Virkon S, EPA Reg. No. 62432-1.

A Reregistration Eligibility Decision (RED), Case number 4072, was issued in December of 1993 for the Technical Grade Active Ingredient (TGAI), Peroxy Compounds, which includes the active ingredients Hydrogen Peroxide, Peroxyacetic Acid, and Potassium Peroxymonosulfate Sulfate. The generic data base supporting the reregistration of the Peroxy Compounds for the eligible uses specified in the RED, has been reviewed and found to be substantially complete.

#### FINDINGS:

1. The information concerning the analytical methods for the analysis of Potassium peroxymonosulfate and Sodium chloride are adequate and satisfy the data requirements under GRN 830-1800, Enforcement Analytical Method.
2. The CSF, a basic formulation dated 03/22/01 is acceptable as presented. The nominal concentration of Potassium peroxymonosulfate and Sodium chloride agree with that on the label. The proposed certified limits are the standard limits as specified in 40CFR 158.175 (b)(2). All ingredients presented on the CSF are cleared for use in pesticide formulations. This CSF supersedes the previously submitted basic formulation dated 09/07/94, mentioned in the previous review dated 11/30/00.
3. The submitted product chemistry data satisfy Series 61, 62 and 63 product chemistry requirements.
- 4a. The Ingredient statement on the label is in compliance with the requirements of 40 CFR 156.10(g) and PR Notice 91-2.
- 4b. The Storage and Disposal must be revised as follows: 1) The subheading "STORAGE" must be preceded by the word "PESTICIDE". 2) The statement, "Do not store in metal containers." must be added to the PESTICIDE STORAGE statements currently on the label. 3) A subheading "PESTICIDE DISPOSAL" and text must be added. 4) The subheading "DISPOSAL" currently on the label must be revised to read

**"CONTAINER DISPOSAL".**

- 4c. The product demonstrates hazards of chemical nature. A PHYSICAL OR CHEMICAL HAZARDS heading must be added to the label with appropriate statements addressing product's hazards of oxidizing capability.

**CONCLUSIONS:**

The registrant has satisfied product chemistry data requirements for the reregistration of Virkon S, EPA Reg. No. 62432-1.

**NOTE TO CRM:**

The suggested revisions to the label (Findings 4b and 4c) may be addressed during label review.



**REVIEW OF PRODUCT CHEMISTRY DATA:****PRODUCT NAME: Virkon S****EPA Reg. No: 62432-1****Group A: Series 830-Product Identity, Composition, and Analysis (40 CFR158.155, .160, .165, .167, .170, .175 & .180).****830-1550 Product Identity and Composition**

This product has a label claim nominal concentration of 21.42% potassium peroxymonosulfate, 1.50% sodium chloride, and 77.08% inert ingredients.

**830-1600 Description of Materials Used to Produce the Product**

Refer to Confidential Appendix A.

**830-1620 Discussion of Formulation Process**

Refer to Confidential Appendix A.

**830-1670 Discussion of Formation of Impurities**

Refer to Confidential Appendix A.

**830-1700 Preliminary Analysis**

Refer to Confidential Appendix A

**830-1750 Certified Limits**

Refer to Confidential Appendix A.

**830-1800 Enforcement of Analytical Method:**

The analytical method for potassium peroxymonosulfate is presented in MRID number 410574-01. The principle of the method states: "The Iodine released from an acidic potassium iodide solution by an active oxygen is titrated with sodium thiosulfate to a colorless end point." A 0.3g sample is weighed into a small glass sample cup and added into a 100 mL sulfuric acid solution. Ten mL of potassium iodide solution is added and the mixture is swirled to mix. The solution is immediately titrated with 0.1N sodium thiosulfate to the disappearance of the blue color. Sodium chloride is determined by weighing a 0.2 g of sodium chloride and dissolving in 35 mL of water. Fifteen milliliters of dilute nitric acid, 5 mL of dibutyl phthalate and 50mL of 0.1M silver nitrate are added and the solution is shaken vigorously for about one minute. Five mL of 10% w/v aqueous solution of ferric ammonium sulfate is added and the solution is titrated with 0.1N ammonium thiocyanate to a reddish-brown color, which persists for five minutes after shaking. The oxidizing power of *Virkon S* is determined by the measure of its available oxygen (Available Chlorine). Available chlorine is determined by dissolving a product sample in water, adding potassium iodide crystals and 10% acetic acid. The liberated iodine is titrated with 0.1N sodium thiophosphate to a colorless endpoint. Sample calculations were included.

These methods are found to be acceptable to support the reregistration of this product.

Group B: Series 830- Physical and Chemical Properties (40 CFR 158.190); MRID No.: 420924-01, 410574-01, unless indicated

GUIDELINE REFERENCE NO. (GRN)/ TITLE 830	VALUE OR QUALITATIVE DESCRIPTION/ METHOD(S) USED WHERE APPLICABLE AND REFERENCES
-6302 Color	Virkon S - White Potassium monopersulfate - White NaCl - Colorless
-6303 Physical State	Virkon S, Potassium monopersulfate and NaCl - Solid
-6304 Odor	Virkon S, Potassium monopersulfate and NaCl - Odorless
-6313 Stability	Potassium monopersulfate and NaCl - "Stable"
-6314 Oxidation/Reduction: Chemical Incompatibility	No apparent reaction was noted when tested with water, iron, kerosene. Not expected to react with carbon dioxide and monoammonium phosphate since the product contains sodium salt of a phosphate. Effervescence, accompanied by slight chlorine odor was noted when tested with potassium permanganate solution. All testing were conducted for 24 hours at 20°. The subject product was determined to be a weak oxidizer.
-6315 Flammability/Flame Extension	Not applicable.
-6316 Explodability	"Does not explode."
-6317 Storage Stability	Results of the studies initiated in 1988 and 1989 conducted on 6 lots of the product indicate that the product is stable for up to three years at room temperature.
-6319 Miscibility	Not applicable ("Not a miscible liquid").
-6320 Corrosion Characteristics	Product was found to be non-corrosive to its packaging (made of HDPE materials) after one, two, and three years of storage at room temperature.
-6321 Dielectric Breakdown Voltage	Not applicable, product is not labeled to be used around electrical equipments.
-7000 pH	Virkon S - 2.3 - 2.7 Potassium monopersulfate - 2.3 NaCl - 6.7 - 7.3
-7100 Viscosity	N/A, product is a solid.
-7200 Melting Point	Potassium monopersulfate - 235°C (from the RED) NaCl - 801°C



-7220 Boiling Point	Potassium monopersulfate - "decomposes" before boiling (from the RED) NaCl - N/A
-7300 Density/Relative Density/Bulk Density	56-62 lbs/cu.ft. (Virkon S) Specific gravity (potassium monopersulfate) - 1.1-1.4g/cc 2.165 g/cc (NaCl)
-7370 Dissociation Constant in Water	"N/A"
-7550 Octanol/Water Partition Coefficient	"N/A"
-7840 Water Solubility	Potassium monopersulfate - 25.6% @ 20°C NaCl - 35.7 g/100cc @ 0°C 39.12 g/100cc @ 100°C
-7950 Vapor Pressure	Potassium monopersulfate - "Nil" NaCl - 1 mm @ 865°C

**Confidential Appendix A****830-1600 Description of Materials Used to Produce the Product**

The materials used in the formulation of this product are listed in the CSF, a basic formulation dated 03/22/01. The beginning materials are also presented in MRID number 410574-01. MSDSs for each material were also included.

**830-1650 Description of Formulation Process**

The manufacture of Virkon S is summarized in MRID number 410574-01 as follows:

**830-1670 Discussion of Formation of Impurities****830-1700 Preliminary Analysis**

Not required for non-integrated products.

**830-1750 Certified Limits**

Potassium peroxydisulfate: Lower Limit: 20.78%; Nominal Conc.: 21.42%; Upper Limit: 22.07%  
Sodium Chloride: Lower Limit: 1.42%; Nominal Conc.: 1.50%; Upper Limit: 1.58%



DATE OUT: 28/MAR/01

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Manufacturing Use [ ], End Use Product [x]

BARCODE No.: D272683 EPA RECEIVED DATE: 01/31/01 Reg./File Symbol No.: 62432-1

PRODUCT NAME: Virkon S

MRID numbers: 420924-01, 411083-00, -01, -02, 413821-00, -01, 410574-00, -01, 412597-01

COMPANY NAME: Antec International, Ltd

Action Code: 675

FROM: Maria Rivera Piansay, Chemist  
Product Chemistry Team  
PRB/SRRD (7508C)

*Maria Rivera Piansay*  
03/28/01

TO: Veronica Dutch, CRM  
Product Reregistration Branch  
Special Review and Reregistration Division (7508C)

### INTRODUCTION:

Antec International, Ltd. submitted the MRID numbers 420924-01, 411083-00, -01, -02, 413821-00, -01, 410574-00, -01, and 412597-01, a basic formulation CSF dated 03/22/01, and a draft label EPA received 03/23/01, in response to a previous product chemistry review by SRRD/PRB (dated 11/30/00, Barcode number D270554) wherein Series 61, 62 and 63 product chemistry requirements were cited as data gaps for the reregistration of Virkon S, EPA Reg. No. 62432-1.

A Reregistration Eligibility Decision (RED), Case number 4072, was issued in December of 1993 for the Technical Grade Active Ingredient (TGAI), Peroxy Compounds, which includes the active ingredients Hydrogen Peroxide, Peroxyacetic Acid, and Potassium Peroxymonosulfate Sulfate. The generic data base supporting the reregistration of the Peroxy Compounds for the eligible uses specified in the RED, has been reviewed and found to be substantially complete.

### FINDINGS:

1. The information concerning the analytical methods for the analysis of Potassium peroxymonosulfate and Sodium chloride are adequate and satisfy the data requirements under GRN 830-1800, Enforcement Analytical Method.
2. The CSF, a basic formulation dated 03/22/01 is acceptable as presented. The nominal concentration of Potassium peroxymonosulfate and Sodium chloride agree with that on the label. The proposed certified limits are the standard limits as specified in 40CFR 158.175 (b)(2). All ingredients presented on the CSF are cleared for use in pesticide formulations. This CSF supersedes the previously submitted basic formulation dated 09/07/94, mentioned in the previous review dated 11/30/00.
3. The submitted product chemistry data satisfy Series 61, 62 and 63 product chemistry requirements.
- 4a. The Ingredient statement on the label is in compliance with the requirements of 40 CFR 156.10(g) and PR Notice 91-2.
- 4b. The Storage and Disposal must be revised as follows: 1) The subheading "STORAGE" must be preceded by the word "PESTICIDE". 2) The statement, "Do not store in metal containers." must be added to the PESTICIDE STORAGE statements currently on the label. 3) A subheading "PESTICIDE DISPOSAL" and text must be added. 4) The subheading "DISPOSAL" currently on the label must be revised to read

"CONTAINER DISPOSAL".

- 4c. The product demonstrates hazards of chemical nature. A PHYSICAL OR CHEMICAL HAZARDS heading must be added to the label with appropriate statements addressing product's hazards of oxidizing capability.

**CONCLUSIONS:**

The registrant has satisfied product chemistry data requirements for the reregistration of Virkon S, EPA Reg. No. 62432-1.

**NOTE TO CRM:**

The suggested revisions to the label (Findings 4b and 4c) may be addressed during label review.



**REVIEW OF PRODUCT CHEMISTRY DATA:****PRODUCT NAME:** Virkon S**EPA Reg. No:** 62432-1**Group A: Series 830-Product Identity, Composition, and Analysis (40 CFR158.155, .160, .165, .167, .170, .175 & .180).****830-1550 Product Identity and Composition**

This product has a label claim nominal concentration of 21.42% potassium peroxymonosulfate, 1.50% sodium chloride, and 77.08% inert ingredients.

**830-1600 Description of Materials Used to Produce the Product**

Refer to Confidential Appendix A.

**830-1620 Discussion of Formulation Process**

Refer to Confidential Appendix A.

**830-1670 Discussion of Formation of Impurities**

Refer to Confidential Appendix A.

**830-1700 Preliminary Analysis**

Refer to Confidential Appendix A

**830-1750 Certified Limits**

Refer to Confidential Appendix A.

**830-1800 Enforcement of Analytical Method:**

The analytical method for potassium peroxymonosulfate is presented in MRID number 410574-01. The principle of the method states: "The iodine released from an acidic potassium iodide solution by an active oxygen is titrated with sodium thiosulfate to a colorless end point." A 0.3g sample is weighed into a small glass sample cup and added into a 100 mL sulfuric acid solution. Ten mL of potassium iodide solution is added and the mixture is swirled to mix. The solution is immediately titrated with 0.1N sodium thiosulfate to the disappearance of the blue color. Sodium chloride is determined by weighing a 0.2 g of sodium chloride and dissolving in 35 mL of water. Fifteen milliliters of dilute nitric acid, 5 mL of dibutyl phthalate and 50mL of 0.1M silver nitrate are added and the solution is shaken vigorously for about one minute. Five mL of 10% w/v aqueous solution of ferric ammonium sulfate is added and the solution is titrated with 0.1N ammonium thiocyanate to a reddish-brown color, which persists for five minutes after shaking. The oxidizing power of *Virkon S* is determined by the measure of its available oxygen (Available Chlorine). Available chlorine is determined by dissolving a product sample in water, adding potassium iodide crystals and 10% acetic acid. The liberated iodine is titrated with 0.1N sodium thiophosphate to a colorless endpoint. Sample calculations were included.

These methods are found to be acceptable to support the reregistration of this product.

Group B: Series 830- Physical and Chemical Properties (40 CFR 158.190); MRID No.: 420924-01, 410574-01, unless indicated

GUIDELINE REFERENCE NO. (GRN)/ TITLE 830	VALUE OR QUALITATIVE DESCRIPTION/ METHOD(S) USED WHERE APPLICABLE AND REFERENCES
-6302 Color	Virkon S - White Potassium monopersulfate - White Na Cl - Colorless
-6303 Physical State	Virkon S, Potassium monopersulfate and NaCl - Solid
-6304 Odor	Virkon S, Potassium monopersulfate and NaCl - Odorless
-6313 Stability	Potassium monopersulfate and NaCl - "Stable"
-6314 Oxidation/Reduction: Chemical Incompatibility	No apparent reaction was noted when tested with water, iron, kerosene. Not expected to react with carbon dioxide and monoammonium phosphate since the product contains sodium salt of a phosphate. Effervescence, accompanied by slight chlorine odor was noted when tested with potassium permanganate solution. All testing were conducted for 24 hours at 20°. The subject product was determined to be a weak oxidizer.
-6315 Flammability/Flame Extension	Not applicable.
-6316 Explodability	"Does not explode."
-6317 Storage Stability	Results of the studies initiated in 1988 and 1989 conducted on 6 lots of the product indicate that the product is stable for up to three years at room temperature.
-6319 Miscibility	Not applicable ("Not a miscible liquid").
-6320 Corrosion Characteristics	Product was found to be non-corrosive to its packaging (made of HDPE materials) after one, two, and three years of storage at room temperature.
-6321 Dielectric Breakdown Voltage	Not applicable, product is not labeled to be used around electrical equipments.
-7000 pH	Virkon S - 2.3 - 2.7 Potassium monopersulfate - 2.3 NaCl - 6.7 - 7.3
-7100 Viscosity	N/A, product is a solid.
-7200 Melting Point	Potassium monopersulfate - 235°C (from the RED) NaCl - 801°C



-7220 Boiling Point	Potassium monopersulfate - "decomposes" before boiling (from the RED) NaCl - N/A
-7300 Density/Relative Density/Bulk Density	56-62 lbs/cu.ft. (Virkon S) Specific gravity (potassium monopersulfate) - 1.1-1.4g/cc 2.165 g/cc (NaCl)
-7370 Dissociation Constant in Water	"N/A"
-7550 Octanol/Water Partition Coefficient	"N/A"
-7840 Water Solubility	Potassium monopersulfate - 25.6% @ 20°C NaCl - 35.7 g/100cc @ 0°C 39.12 g/100cc @ 100°C
-7950 Vapor Pressure	Potassium monopersulfate - "Nil" NaCl - 1 mm @ 865°C

### Confidential Appendix A

#### 830-1600 Description of Materials Used to Produce the Product

The materials used in the formulation of this product are listed in the CSF, a basic formulation dated 03/22/01. The beginning materials are also presented in MRID number 410574-01. MSDSs for each material were also included.

#### 830-1650 Description of Formulation Process

The manufacture of Virkon S is summarized in MRID number 410574-01 as follows: a)

#### 830-1670 Discussion of Formation of Impurities

#### 830-1700 Preliminary Analysis

Not required for non-integrated products.

#### 830-1750 Certified Limits

Potassium peroxymonosulfate: Lower Limit: 20.78%; Nominal Conc.: 21.42%; Upper Limit: 22.07%  
Sodium Chloride: Lower Limit: 1.42%; Nominal Conc.: 1.50%; Upper Limit: 1.58%



DATE OUT: 30/NOV/00

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Manufacturing Use [ ], End Use Product [x]

BARCODE No.: D270554 EPA RECEIVED DATE: 04/20/94 Reg./File Symbol No.: 62432-1

PRODUCT NAME: Virkon S MRID number: 405815-01, -02, -03

COMPANY NAME: Antec International, Ltd Action Code: 674

FROM: Maria Rivera Piansay, Chemist  
Product Chemistry Team  
PRB/SRRD (7508C)

*Maria Rivera Piansay*  
11/30/00

TO: Veronica Dutch, CRM  
Product Reregistration Branch  
Special Review and Reregistration Division (7508C)

### INTRODUCTION:

Antec International, Ltd. submitted a CSF for the basic formulation dated 09/07/94, a product label EPA received 10/04/94, and product chemistry data in MRID numbers 405815-01, 405815-02, 405815-03. The registrant is requesting FIFRA Section 4 reregistration of **Virkon S**, EPA Reg. No. 62432-1.

A Reregistration Eligibility Decision (RED), Case number 4072, was issued in December of 1993 for the Technical Grade Active Ingredient (TGAI), Peroxy Compounds, which includes the active ingredients Hydrogen Peroxide, Peroxyacetic Acid, and Potassium Peroxymonosulfate Sulfate. The generic data base supporting the reregistration of the Peroxy Compounds for the eligible uses specified in the RED, has been reviewed and found to be substantially complete.

### FINDINGS:

1. For most of the physical and chemical properties, the data submitted do not support the reregistration requirements for the subject product, because the data submitted are those of "Oxone Monopersulfate Compound" (45% Triple Salt, Oxone), rather than the data for "Virkon S". The registrant should be advised to submit product-specific data for the following: **Color** (830-6302), **Physical state** (830-6303), **Odor** (830-6304), **Oxidation/Reduction: Chemical Incompatibility** (830-6314), **Flammability/Flame Extension** (830-6315), **Explosibility** (830-6316), **Viscosity** (830-7100), if product is a liquid, **Description of Formulation Process** (830-1650), **Discussion of Formation of Impurities** (830-1670), **Enforcement Analytical Method** (GRN 830-1800), and the one-year, room temperature **Storage Stability** (830-6317) and **Corrosion Characteristics** (830-6320). The registrant may submit waiver requests if any of these studies do not apply to the product and/or they may cite MRID numbers or studies that would support this product.
2. Comments on the CSF and the label will be deferred until all product chemistry data have been reviewed.

### CONCLUSIONS:

After resolution of Findings 1 and 2, the registrant will satisfy product chemistry data requirements for the reregistration of **Virkon S**. EPA Reg. No. 62432-1



January 19, 2001

Ms. Linda Propst, Chief  
Product Reregistration Branch, SRRD  
US EPA  
Washington, DC 20460

Subject: EPA Reg. No. 62432-1; Your Letters Dated December 18, 2000; Review of Product Chemistry Data; Review of Acute Toxicity Data

Dear Ms. Propst:

Thank you for your letters of December 18 noting deficiencies in the product chemistry and acute toxicity data supporting reregistration of Virkon S (EPA Reg. No. 62432-1). The previous Agent for Antec International Ltd., Dr. Alan Wagner, apparently cited data on the principal active ingredient, potassium peroxymonosulfate, in his last filing rather than on the formulation itself. Since that filing, I have replaced Dr. Wagner as Antec's Agent.

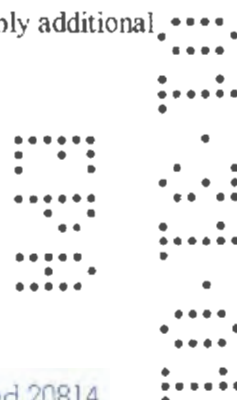
When the original application for registration of Virkon S was submitted, Antec's US distributor, a subsidiary of A.H. Robins Corporation, took responsibility for collecting the necessary data and gaining registration. Antec was supplied with copies of some of the registration documents but none of the underlying data. In 1992, Antec terminated its agreement with its distributor and the registration was transferred to Antec. At that time, it was the parties' intention to transfer data rights but that did not occur. Since Antec possessed no copies of the original product chemistry and acute toxicity data and had no role in collection of this data, Dr. Wagner was apparently not aware of its existence.

In the meantime, I had become aware of the existence of product-specific data as I prepared an application for registration for a product identical in formulation, Virkon (EPA Reg. No. 62432-2). The attached data matrix now references this data on the Virkon S formulation. Because Antec does not possess copies of the data itself, I am unable to determine which product chemistry information is contained in each of the two product chemistry submissions previously made. Consequently I have referenced both MRID numbers for each data requirement. I would be happy to revise the product chemistry portion of the data matrix if you can provide me with guidance in doing so based on your review of the actual documents.

Let me know if you have any questions regarding this submission or if I need to supply additional information.

Sincerely,

T. Jeffrey Jones, Agent  
Antec International Ltd.  
Enclosures



7910 Woodmont Avenue, Suite 1000, Bethesda, Maryland 20814  
(301) 652-5400 FAX (301) 652-5408





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

258529

## Application for Pesticide - Section I

1. Company/Product Number 62432-1	2. EPA Product Manager Veronica Dutch, CRM	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Virkon S	PM#	
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd. c/o Delta Analytical Corp. 7910 Woodmont Ave., Suite 1000 Bethesda, MD 20814  <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____  Product Name _____

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>18 DEC 00</u>	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Annotation: Use additional pages if necessary. (For section I and Section II.)

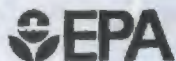
## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Jeff Jones		Title Agent, Antec International Ltd.		Telephone No. (Include Area Code) 301 652 5495	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.					6. Date Application Received (Stamped)    
2. Signature 		3. Title Agent, Antec International Ltd.			
4. Typed Name Jeff Jones		5. Date 19 JAN 01			





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

258529

## Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code)  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.      No. per container	If "Yes" Package wgt.      No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name		Title	
		Telephone No. (Include Area Code) .....	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			
2. Signature		3. Title	
4. Typed Name		5. Date	
6. Date Application Received (Stamped) ..... ..... .....			



## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

**Submission of Labeling** - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data** - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A** - Check the appropriate action for which you are submitting this form.

**SECTION I** - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II** - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III** (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

**SECTION IV** (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Antec International Ltd. c/o Delta Analytical Corporation; 301 652 5495	EPA Registration Number/File Symbol 62432-1
Active Ingredient(s) and/or representative test compound(s) potassium peroxydisulfate; sodium chloride	Date 19 January 2001
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor	Product Name Virkon S

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☒ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date 19 JAN 01	Typed or Printed Name and Title Jeff Jones, Agent, Antec International Ltd.
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 19 January 2001	EPA Reg No./File Symbol 62432-1	Page 1 of 2
Applicant's/Registrant's Name & Address Antec International Ltd. c/o Delta Analytical Corp., 7910 Woodmont Ave., Ste. 1000, Bethesda, MD 20814	Product Virkon S	

Ingredient potassium peroxymonosulfate; sodium chloride

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-6302	Color	see Note 1	A. H. Robins	PER	2
830-6303	Physical state	-Do-	-Do-	-Do-	-Do-
830-6304	Odor	-Do-	-Do-	-Do-	-Do-
830-6314	Oxidation/Reduction	-Do-	-Do-	-Do-	-Do-
830-6315	Flammability/Flame extension	N/A			3
830-6316	Explosibility	N/A			4
830-7100	Viscosity	N/A			5
830-1650	Description of formulation process	-Do-	A. H. Robins	-Do-	-Do-
830-1670	Discussion of formation of impurities	-Do-	-Do-	-Do-	-Do-
830-1800	Enforcement analytical method	-Do-	-Do-	-Do-	-Do-
830-6317	Storage stability	-Do-	-Do-	-Do-	-Do-
830-6320	Corrosion characteristics	-Do-	-Do-	-Do-	-Do-

Signature 	Name and Title Jeff Jones, Agent, Antec International Ltd.	Date 19 JAN 01
--	---	-------------------





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

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### DATA MATRIX

Date 19 January 2000

EPA Reg No./File Symbol 62432-1

Page 2 of 2

**Applicant's/Registrant's Name & Address**

Product

Antec International Ltd, c/o Delta Analytical Corp., 7910 Woodmont Ave., Ste. 1000, Bethesda, MD 20814

## Virkon S

**Ingredient** potassium peroxymonosulfate; sodium chloride

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
81-1	Acute oral toxicity	41057402	A. H. Robins	PER	2
81-2	Acute dermal toxicity	41057403	-Do-	-Do-	
81-3	Acute inhalation toxicity	41057404	-Do-	-Do-	
81-4	Primary skin irritation	41057405	-Do-	-Do-	
81-4	Primary skin irritation	41057406	-Do-	-Do-	
81-5	Primary eye irritation	41057407	-Do-	-Do-	
81-5	Primary eye irritation	41057408	-Do-	-Do-	
81-6	Skin sensitization	41057409	-Do-	-Do-	
Signature			Name and Title		Date
Jeff Jones			Jeff Jones, Agent, Antec International Ltd.		19 JAN 01



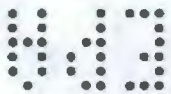

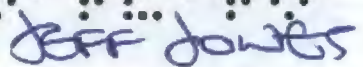


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 19 January 2001	EPA Reg No./File Symbol 62432-1	Page 1 of 2	
Applicant's/Registrant's Name & Address Antec International Ltd. c/o Delta Analytical Corp., 7910 Woodmont Ave., Ste. 1000, Bethesda, MD 20814	Product Virkon S		
Ingredient potassium peroxymonosulfate; sodium chloride			
 	Submitter	Status	Note
	A. H. Robins	PER	2
	-Do-	-Do-	-Do-
	-Do-	-Do-	-Do-
	-Do-	-Do-	-Do-
			3
			4
			5
	A. H. Robins	-Do-	-Do-
	-Do-	-Do-	-Do-
	-Do-	-Do-	-Do-
	-Do-	-Do-	-Do-
	-Do-	-Do-	-Do-
Signature 	Name and Title Jeff Jones, Agent, Antec International Ltd.	Date 19 JAN 01	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 19 January 2000

EPA Reg No./File Symbol 62432-1

Page 2 of 2

Applicant's/Registrant's Name & Address

Antec International Ltd, c/o Delta Analytical Corp., 7910 Woodmont Ave., Ste. 1000, Bethesda, MD 20814

Product

Virkon S

Ingredient potassium peroxymonosulfate; sodium chloride

Submitter	Status	Note
A. H. Robins	PER	2
-Do-	-Do-	
-Do-	-Do-	
-Do-	-Do-	
-Do-	-Do-	
-Do-	-Do-	
-Do-	-Do-	
-Do-	-Do-	
-Do-	-Do-	

Signature

Jeff Jones

Name and Title

Jeff Jones, Agent, Antec International Ltd.

Date

19 JAN 01





## AMERICAN HOME PRODUCTS CORPORATION

FIVE GIRALDA FARMS, MADISON, NEW JERSEY 07940 (973) 660-6535, FAX (973) 660-7176

January 17, 2001

**TIMOTHY T. SLATER**  
ASSOCIATE GENERAL COUNSEL

Ms. Linda S. Propst, Chief  
Product Registration Branch, SRRD  
Office of Pesticide Programs  
US Environmental Protection Agency  
Washington DC, 20460

Dear Ms. Propst:

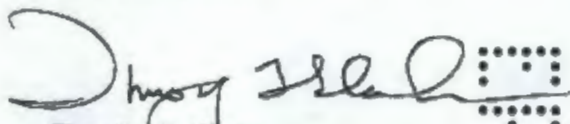
A. H. Robins Company ("Robins") is a subsidiary of American Home Products Corporation and I am counsel to and Assistant Secretary of Robins. In those capacities I am writing on behalf of Robins to grant Antec International Ltd., Chilton Industrial Estate, Sudbury, Suffolk CO10 6XD, England permission to cite data listed in Attachment I presently owned by Robins. I understand this data will be cited in support of reregistration of Virkon S (EPA Reg. No. 62432-1) and Virkon (EPA Reg. No. 62432-2).

As the original registrant of Virkon S (EPA Reg. No. 778-91), Robins submitted extensive data in support of its registration. The registration itself was officially transferred to Antec International in 1992. At that time, the intent was to transfer data rights as well, but I understand that has not been formally accomplished. Robins will be submitting the appropriate documents to accomplish that objective shortly.

In the interim, Robins grants Antec permission to cite all Virkon S data presently owned by Robins.

If you have any questions regarding this matter, please contact me.

Very truly yours,

  
Timothy T. Slater



cc: Jeff Jones, Delta Analytical Corporation

## SCHEDULE A

### Bibliography of Data Subject to Transfer Agreement between A.H. Robins Company and Antec International Ltd.

41259700 A.H. Robbins Co. (1989) Submission of Data To Support Registration  
of Virkon S: Product Performance Study. Transmittal of 1 study.

SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 10/10/89    ACCSN: 412597 00  
EXCLUSIVE USE STUDY expiring 10/09/99

41259701 Prince, D. (1989) Laboratory Report: Primary Registration AOAC  
Dilution on Virkon S Powder: Lab Project Nos:48881: 262-174-895.  
Unpublished study prepared by Gibraltar Biological Laboratories,  
Inc. 19 p.

SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 10/10/89    ACCSN: 412597 01  
EXCLUSIVE USE STUDY expiring 10/09/99

41108300 A.H. Robbins Co. (1989) Submission of Data To Support Amendment to  
Application for Registration of VirKon S: Efficacy Data. Trans-  
mittal of 2 studies.

SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 05/23/89    ACCSN: 411083 00  
EXCLUSIVE USE STUDY expiring 5/22/99

42092400 A.H. Robbins Co. (1991) Submission of product chemistry data in  
support of registration of Virkon S. Transmittal of 1 study.

SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 11/15/91    ACCSN: 420924 00  
EXCLUSIVE USE STUDY expiring 11/14/2001

42092401 Lybrand, R.; Szulczewski, D. (1991) Product Chemistry: Virkon S.  
Unpublished study prepared by A. H. Robbins Co. 16 p.

SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 11/15/91    ACCSN: 420924 01  
EXCLUSIVE USE STUDY expiring 11/14/2001

41108301 Prince, D. (1989) Laboratory Report; Virucidal Assay--EPA Method:  
Report No. 49325; Study Nos. 554-161-2565; 551-161-2544. Unpu-  
blished study prepared by Gibraltar Biological Laboratories,  
Inc. 16 p.

SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 05/23/89    ACCSN: 411083 01  
EXCLUSIVE USE STUDY expiring 5/22/99



41108302 Prince, D. (1989) Laboratory Report: Virucide Assay--EPA Method: VirKon S: Report No. 49324: Study No. 554-161-2565. Unpublished study prepared by Gibraltar Biological Laboratories, Inc. 16 p.

SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 05/23/89    ACCSN: 411083 02  
EXCLUSIVE USE STUDY expiring 5/22/99

41382100 A.H. Robins Co. (1989) Submission of Efficacy Data to Support the Amended Registration of Virkon S Disinfectant. Transmittal of 1 study.

SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 02/07/90    ACCSN: 413821 00  
EXCLUSIVE USE STUDY expiring 2/6/2000

41382101 Prince, D. (1989) Disinfectant Screening Testing: AOAC Use Dilution Test: Virkon S Disinfectant: Report No. 52905: GBL Study No. GR59. Unpublished study prepared by Gibraltar Biological Laboratories. 13 p.

SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 02/07/90    ACCSN: 413821 01  
EXCLUSIVE USE STUDY expiring 2/06/2000

41057400 A.H. Robins Co. (1989) Submission of Product Chemistry and Toxicity Data to Support the Continued Registration of VirKon-S. Transmittal of 11 studies.

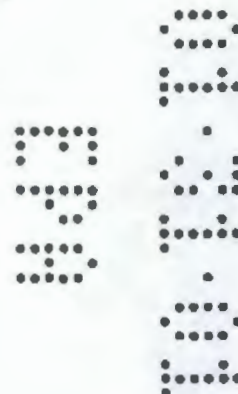
SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 04/07/89    ACCSN: 410574 00  
EXCLUSIVE USE STUDY expiring 4/06/99

41057401 A.H. Robins Co. (1989) Product Chemistry Data for VirKon-S and Its Active Ingredients: Laboratory Project Product Data for VirKon-S. Unpublished study. 32 p.

SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 04/07/89    ACCSN: 410574 01  
EXCLUSIVE USE STUDY expiring 4/06/99

41057402 Gabriel, D. (1989) VirKon-S, A.H. Robins Disinfectant, Lot No. 02809160...Acute Oral Toxicity, LD50-Rats: Biosearch Project No. 88-6437A. Unpublished study prepared by Biosearch, Inc. 19 p.

SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 04/07/89    ACCSN: 410574 02  
EXCLUSIVE USE STUDY expiring 4/06/99



41057403 Gabriel, D. (1988) VirKon-S, A.H. Robins Disinfectant, Lot No. 02809160...Acute Dermal Toxicity, LD50--Rabbits: Biosearch Project No. 68-6437A. Unpublished study prepared by Biosearch, Inc. 8 p.

SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 04/07/89    ACCSN: 410574 03  
EXCLUSIVE USE STUDY expiring 4/06/99

41057404 Hershman, R. (1988) VirKon-S, A.H. Robins Disinfectant, Lot No. 02809160...Acute Inhalation Toxicity, Single Level, 4 Hour Exposure--Rats: Biosearch Project No. 88-6437A. Unpublished study prepared by Biosearch, Inc. 21 p.

SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 04/07/89    ACCSN: 410574 04  
EXCLUSIVE USE STUDY expiring 4/06/99

41057405 Moore, G. (1988) VirKon-S, A.H. Robins Disinfectant, Lot No. 02809160...Primary Eye Irritation--Rabbits: Biosearch Project No. 88-6437A. Unpublished study prepared by Biosearch, Inc. 11 p.

SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 04/07/89    ACCSN: 410574 05  
EXCLUSIVE USE STUDY expiring 4/06/99

41057406 Moore, G. (1988) VirKon-S, A.H. Robins Disinfectant, Lot No. 02809160...Primary Eye Irritation--Rabbits: Biosearch Project No. 88-6437A. Unpublished study prepared by Biosearch, Inc. 11 p.

SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 04/07/89    ACCSN: 410574 06  
EXCLUSIVE USE STUDY expiring 4/06/99

41057407 Gabriel, D. (1988) VirKon-S, A.H. Robins Disinfectant, Lot No. 02809160...Primary Skin Irritation--Rabbits: Biosearch Project No. 88-6437A. Unpublished study prepared by Biosearch, Inc. 9 p.

SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 04/07/89    ACCSN: 410574 07  
EXCLUSIVE USE STUDY expiring 4/06/99

41057408 Gabriel, D. (1988) VirKon-S, A.H. Robins Disinfectant, Lot No. 02809160...Primary Skin Irritation--Rabbits: Biosearch Project No. 88-6437A. Unpublished study prepared by Biosearch, Inc. 8 p.

SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 04/07/89    ACCSN: 410574 08  
EXCLUSIVE USE STUDY expiring 4/06/99



41057409 Daniels, D. (1989) VirKon-S, A.H. Robins Disinfectant, Lot No. 02809160... Guinea Pig Dermal Sensitization--Modified Buehler Method: Biosearch Project No. 88-6437A. Unpublished study prepared by Biosearch, Inc. 16 p.

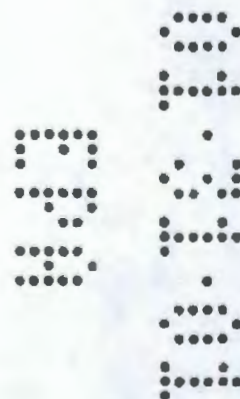
SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 04/07/89    ACCSN: 410574 09  
EXCLUSIVE USE STUDY expiring 4/06/99

41057411 Prince, D. (1989) Primary Registration: AOAC Use Dilution of Virkon S Powder Disinfectant: AOAC Use Dilution Test: GBL Study No. 264-174-895. Unpublished study prepared by Gibraltar Biological Laboratories, Inc. 18 p.

SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 04/07/89    ACCSN: 410574 11  
EXCLUSIVE USE STUDY expiring 4/06/99

41057410 Prince, D. (1989) EPA Supplemental Registration of Virkon S Disinfectant: AOAC Use Dilution Test: GBL Study No. 264-174-923. Unpublished study prepared by Gibraltar Biological Laboratories, Inc. 15 p.

SUBMITTED BY: 000778    ADMIN-NR: 000778-91  
DATE: 04/07/89    ACCSN: 410574 10  
EXCLUSIVE USE STUDY expiring 4/06/99



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 18 2000

Antec International LTD.  
C/O Delta Analytical Corporation  
7910 Woodmont Avenue #1000  
Bethesda, MD 20814  
Attn: T. Jeffrey Jones

Subject: Review of Product Chemistry Data, MRID Numbers 405815-01, 405815-02 and 405815-03 for Peroxy Compounds Reregistration Eligibility Decision (RED), EPA Reg. No. 62432-1.

Dear Mr. Jones:

The Agency has received your submission of product chemistry data for the reregistration of EPA Reg. No. 62432-1 and has made the following determinations:

1. For most of the physical and chemical properties, the data submitted do not support the reregistration requirements for the subject product, because the data submitted are those of "Oxone Monopersulfate Compound" (45% Triple Salt, Oxone), rather than the data for Virkon S". You must submit or cite studies for the following requirements: Color (Guideline 830-6302), Physical State (Guideline 830-6303), Odor (Guideline 830-6304), Oxidation/Reduction: Chemical Incompatibility (Guideline 830-6314), Flammability/Flame Extension (Guideline 830-6315), Explodability (Guideline 830-6316), Viscosity (Guideline 830-7100), if product is a liquid, Description of Formulation Process (Guideline 830-1650), Discussion of Formation of Impurities (Guideline 830-1670), Enforcement Analytical Method (Guideline 830-1800), and the one year, room temperature Storage Stability (Guideline 830-6317) and Corrosion Characteristics (Guideline 830-6320). You may submit waiver requests if any of these studies do not apply to the product or cite the MRID numbers or studies that would support this product.
2. Comments on the Confidential Statement of Formula (CSF) and the label will be deferred until all product chemistry data have been reviewed.

CONCURRENCES							
SYMBOL	7508C	7508C					
SURNAME	1/Dutch	Proper					
DATE	12-11-00	12/11/00					

EPA Form 1320-1A (1/00) Printed on Recycled Paper OFFICIAL FILE COPY 172  
\*U.S. Government Printing Office: 1992 — 620-856/40672



Adequate data for the studies specified above must be cited within 30 days of receipt of this letter. If you choose to conduct new studies, you must notify the Agency of your intentions within 10 days of receipt of this letter and submit the data within 90 days from receipt of this letter. Failure to respond within these time frames could result in a Notice of Intent to Suspend (NOIS) affecting the reregistration of your product.

A copy of the Agency review of product chemistry data is enclosed with this letter.

Should you have any further questions, please contact Veronica Dutch of my staff at 703-308-8585.

Sincerely,

Linda S. Propst, chief  
Product Reregistration Branch  
Special Review and  
Reregistration Division

Enclosure



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

Antec International LTD.  
C/O Delta Analytical Corporation  
7910 Woodmont Avenue #1000  
Bethesda, MD 20814  
Attn: T. Jeffrey Jones

Subject: Review of Acute Toxicity Data, MRID Numbers 426074-01, 426074-02, 426074-03, 426074-04 and 426074-05 for Peroxy Compounds Reregistration Eligibility Decision (RED), EPA Reg. No. 62432-1.

Dear Mr. Jones:

The Agency has received your submission of acute toxicity data for the reregistration of EPA Reg. No. 62432-1. The submitted studies on acute oral Guideline 81-1, acute dermal Guideline 81-2, acute inhalation Guideline 81-3, primary eye irritation Guideline 81-4, primary skin irritation Guideline 81-5 and skin sensitization Guideline 81-6 are not acceptable. The test material used in the studies is not substantially similar to the subject product, therefore, you must cite other studies or submit studies performed on the subject product.

Adequate data for the studies specified above must be cited within 30 days of receipt of this letter. If you choose to conduct new studies, you must notify the Agency of your intentions within 10 days of receipt of this letter and submit the data within 90 days from receipt of this letter. Failure to respond within these time frames could result in a Notice of Intent to Suspend (NOIS) affecting the reregistration of your product.

A copy of the Agency review of product chemistry data is enclosed with this letter.

**CONCURRENCES**


<b>SYMBOL</b>	7508C							
<b>SURNAME</b>	Prophet							
<b>DATE</b>	12/12/00							



Should you have any further questions, please contact Veronica Dutch of my staff at 703-308-8585.

Sincerely,

Linda S. Propst, chief  
Product Reregistration Branch  
Special Review and  
Reregistration Division



Enclosure

Antec International LTD.  
C/O Delta Analytical Corporation  
7910 Woodmont Avenue #1000  
Bethesda, MD 20814  
Attn: T. Jeffrey Jones

Subject: Review of Acute Toxicity Data, MRID Numbers 426074-01, 426074-02, 426074-03, 426074-04 and 426074-05 for Peroxy Compounds Reregistration Eligibility Decision (RED), EPA Reg. No. 62432-1.

Dear Mr. Jones:

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A copy of the Agency review of product chemistry data is enclosed with this letter.



Should you have any further questions, please contact Veronica Dutch of my staff at 703-308-8585.

Sincerely,

Linda S. Propst, chief  
Product Reregistration Branch  
Special Review and  
Reregistration Division



Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

December 06, 2000

MEMORANDUM:

Subject: EPA Reg. No.: 62432-1/Virkon S  
DP Barcode: D270556  
Case No.: 4072

From: Maria Rivera Piansay, Chemist *Maria Rivera Piansay 12/12/00*  
Product Reregistration Branch  
Special Review and Reregistration Division (7508C) *MTP*

To: Veronica Dutch, CRM  
Product Reregistration Branch  
Special Review and Reregistration Division (7508C)

Applicant: Antec International LTD.  
Chilton Industrial Estate  
Sudbury, Suffolk CO10 6XD  
England

FORMULATION FROM EPA Reg. No. 62432-1 LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Potassium peroxymonosulfate.....	20.4%
Sodium Chloride.....	1.5%
<u>Inert Ingredient(s):</u> .....	78.1%
Total:	100.0%



**BACKGROUND:**

In the 8 month response to the Peroxy Compounds RED, the registrant submitted acute oral, acute dermal, acute inhalation, primary eye irritation, primary skin irritation and skin sensitization studies, in support of the reregistration of Virkon S, EPA Reg. No. 62432-1. The MRID numbers are 426074-01 through -05.

**RECOMMENDATIONS:**

The submitted studies on acute oral, acute dermal, acute inhalation, primary eye irritation, primary skin irritation and dermal sensitization are not acceptable to support this product because the test material used in the studies is not substantially similar to the subject product. The registrant must cite other studies or submit studies performed on the subject product.

The acute toxicity profile for EPA Reg. No. 62432-1 is currently:

Acute Oral	Unacceptable
Acute Dermal	Unacceptable
Acute Inhalation	Unacceptable
Primary Eye	Unacceptable
Primary Dermal	Unacceptable
Skin Sensitization	Unacceptable

**LABELING:** The product labeling will be evaluated upon receipt of acceptable acute toxicity studies.

Page No. 3  
07/15/97

Nancy Tompkins  
308-8013  
SRD/PRB

PRODUCT REREGISTRATION  
WAIVER REQUESTS  
TRACKING REPORT  
(Sorted by Division/Section)

CASE NO.	REG. NO.	WAIVER REQUEST RECEIVED	GUIDELINES REQUESTED TO BE WAIVED	WAIVER REQUEST SENT TO REVIEW	DATE REVIEW RECEIVED	GRANTED OR DENIED	COMMENTS	CRM
** DIVISION AD								
* PH31								
4003	10807-177	07/15/97	91-4, 91-5, 91-2, 91-7, 91-8, 91-2, 91-3	07/17/97	/ /			MA
4072	1677-129	06/10/97	91-2 OK	07/17/97	/ /			VD
4072	1677-158	06/10/97	91-2 NO labels	07/17/97	/ /			VD
4072	1677-159	06/10/97	91-2 OK	07/17/97	/ /			VD
4072	52252-1	06/10/97	91-2 OK NO labels	07/17/97	/ /			VD
4072	52252-5	06/10/97	91-2	07/17/97	/ /			VD
4072	52252-6	06/10/97	91-2	07/17/97	/ /			VD
4072	52252-7	06/10/97	91-2 OK	07/17/97	/ /			VD
4072	58779-1	06/10/97	91-2, 91-2,3, 91-2,7 NO labels	07/17/97	/ /			VD
4072	65402-1	06/10/97	91-2, 91-2,3, 91-2,3, 91-2, 91-2, 91-2 NO labels	07/17/97	/ /			VD



Date: 6/10/97MEMORANDUM

SUBJECT: Request for review of Data Waiver(s) and/or Time Extension(s)  
Submitted in Response to the Product Specific DCI Issued With:

RED (name): Peroxy compds Case #: 4072

TO: Debra McCall, PRS/PCRS/TRB/RD-

PM31 Norm Cook

FROM: Veronica Dutch, CRM  
PRB/SRRD  
Telephone # 308-8585

Please review the attached request(s) for data waiver(s) and/or time extension(s). Please give recommendations for approval, disapproval or other action(s) with rationale/reasons as appropriate.

EPA Product Registration #	GLN#	T W *	Approval/ Disapproval/ Other Action	EPA Product Registration #	GLN#	T W *	Approval/ Disapproval/ Other Action
52252-5	91-2	W		675-39	91-2,3	W	
					91-2	W	
52252-1	91-2	W			91-2	W	
52252-6	91-2	W		65402-1	91-2	W	
					91-2,3	W	
52252-7	91-2	W			91-2,3	W	
					91-2,3	W	
875-107	91-2	W			91-2	W	
					91-2	W	
58779-1	91-2	W			91-2	W	
	91-23	W					
	91-2,7	W					

- \* T = Request for Time extension  
W = Request for data Wavier

Reviewer's Signature

Date

**DR. ALAN R. WAGNER**  
Regulatory Affairs and Technical Services

Private Consultant  
Clinical Investigations

2304 Anhinga Drive  
Kissimmee, Florida 34743

Ph: 407/344-9803  
Fax: 407/344-9980

December 22, 1994

Document Processing Desk (RED-SRRD-4072)  
Office of Pesticide Programs (H7504C)  
U.S. Environmental Protection Agency  
Attention: Ms. Veronica Dutch (H7508W)  
401 N Street S.W.  
Washington, D.C. 20460-0001

Re: DATA CALL-IN RESPONSE  
Peroxy Compounds, Case # 4072-EPA Product  
Registration 62432-1 (Reregistration Eligibility Decision)

Dear Ms. Dutch:

In accord with our recent telephone conversation regarding the **Data Call-In Response** submissions, please find Data Requirement 40 CFR 158.160 Product Performance Section 91-2 as identified in the volumes as listed.

Volume I - Use Dilution Test  
Volume II - Virucidal Effectiveness Test  
Volume III - Fungicidal Efficacy of Virkon S  
Volume IV - Fungicidal Efficacy of Virkon S  
Volume V - Fungicidal Efficacy of Virkon S  
Volume VI - Primary Registration AOAC Use-Dilution on Virkon S Powder  
Volume VII - Disinfectant Screening Testing-AOAC Use Dilution Test  
Volume VIII- The Evaluation of the Efficacy of Virkon S Against *Clostridium perfringens* (vegetative cells)

Regarding the 91-2 comparative product performance data required to be developed and maintained in the registrant's file, Antec International, LTD has initiated an extensive comparative product testing project with ViroMed Laboratories, Inc., 6101 Blue Circle Drive, Minneapolis, MN. The data will be submitted to the agency upon completion in accordance with this requirement.

Again, Ms. Dutch, thank you for your excellent review of our **Data Call-In Response** submissions and your assistance and courtesy extended to me. I hope to have the opportunity to meet with you again during my next visit to your agency.

Sincerely,

*Alan R. Wagner D.V.M., M.S.*  
Alan R. Wagner, D.V.M., M.S.  
Manager Technical, Regulatory Affairs  
Agent for Antec International, LTD

ARW/mw


Express Mail



## APPLICATION FOR RE-REGISTRATION

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A) 	United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number  191021
	Application for Pesticide:		

## Section I

1. Company/Product Number 62432	2. EPA Product Manager Ms. Ruth G. Douglas	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) VIRKON S	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) Antec International, Ltd Chilton Industrial Estate Sudbury, Suffolk CO10 6XD ENGLAND <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No. _____ Product Name _____	

## Section II

<input type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

## Application for Reregistration

Peroxy Compounds, Case # 4072-EPA Product

Registration 62432-1 (RED)

Data Requirements 40 CFR 158.160 Guideline 91-2 (attached)

## Section III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
If "Yes," Unit Package wgt. _____ No. per container _____		If "Yes," Package wgt. _____ No. per container _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container 2.5 Kg. <input type="checkbox"/> 5.0 Kg., 25 Kg., 35 grams <input type="checkbox"/>	
5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product		6. Manner in Which Label Is Affixed To Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Other (Pressure Sensitive)	

## Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Alan R. Wagner D.V.M., M.S.	Title Manager, Regulatory Affairs Agent for Antec International, Ltd.	Telephone No. (Include Area Code) (407) 344-9803
2. Signature Alan R. Wagner D.V.M., M.S.		3. Title Manager, Regulatory Affairs Agent for Antec International, Ltd.
4. Typed Name Alan R. Wagner, D.V.M., M.S.		5. Date December 22, 1994
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)

DATA REQUIREMENTS 40 CFR 158.160, GUIDELINE 91-2

- Use Dilution Test Page 1 of 8
- Virucidal Effectiveness Test Page 1 of 12
- Fungicidal Efficacy of Virkon S Page 1 of 8
- Fungicidal Efficacy of Virkon S Page 1 of 8
- Fungicidal Efficacy of Virkon S Page 1 of 7
- Primary Registration AOAC Use-Dilution on Virkon S Powder Page 1 of 18
- Disinfectant Screening Testing  
AOAC Use Dilution Test Page 1 of 13
- The Evaluation of the Efficacy  
of Virkon S Against *Clostridium*  
*perfringens* (vegetative cells) Page 1 of 7



## C O N T E N T S

	<u>Page</u>
VOLUME I - USE DILUTION TEST .....	1 of 8
VOLUME II - VIRUCIDAL EFFECTIVENESS TEST .....	1 of 12
VOLUME III - FUNGICIDAL EFFICACY OF VIRKON S .....	1 of 8
VOLUME IV - FUNGICIDAL EFFICACY OF VIRKON S .....	1 of 8
VOLUME V - FUNGICIDAL EFFICACY OF VIRKON S .....	1 of 7
VOLUME VI - PRIMARY REGISTRATION AOAC USE- DILUTION ON VIRKON S POWDER .....	1 of 18
VOLUME VII - DISINFECTANT SCREENING TESTING AOAC USE DILUTION TEST .....	1 of 13
VOLUME VIII - THE EVALUATION OF THE EFFICACY OF VIRKON S AGAINST CLOSTRIDIUM PERFRINGENS (VEGETATIVE CELLS).....	1 of 7

Date: 7-11-1997

**MEMORANDUM**

**SUBJECT:** Request for review of Data Waiver(s) and/or Time Extension(s)  
Submitted in Response to the Product Specific DCI Issued With:

RED (name): Pesoxyl Compounds Case #: 4072

**TO:** Debra McCall, PRS/PCRS/TRB/RD

**FROM:** Veronica Dutch, CRM  
PRB/SRRD  
Telephone # 308-8585

*Adam has this as if  
reregistered, check out*

Please review the attached request(s) for data waiver(s) and/or time extension(s). Please give recommendations for approval, disapproval or other action(s) with rationale/reasons as appropriate.

EPA Product Registration #	GLN#	T W •	Approval/ Disapproval/ Other Action	EPA Product Registration #	GLN#	T W •	Approval/ Disapproval/ Other Action
<u>62432-1</u>	<u>81-2</u>	<u>W</u>					
	<u>81-4</u>	<u>W</u>					
	<u>81-5</u>	<u>W</u>					
	<u>81-6</u>	<u>W</u>					

- T = Request for Time extension
- W = Request for data Waiver

\_\_\_\_\_  
Reviewer's Signature Date



# Technical Information

To: ALAN WAGNER  
Company: ANTEC INTERNATIONAL  
Phone: 407-344-9803  
Fax: 407-344-9980

From: BRUCE A. EVANS  
Company: DUPONT SPECIALTY CHEMICALS  
Phone: 302-999-2532  
Fax: 302-999-4396

Date: 13 October 1995

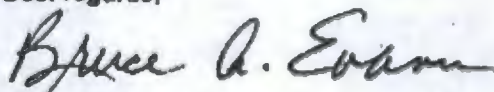
Pages including this one: 2

Attached is a printout of an E-mail note which I received in April from Carol Finley, Supervisor of the dermal study section at Haskell Laboratory. She points out that her recommendation not to run the Primary Dermal Irritation, Primary Eye Irritation, and Acute Dermal Toxicity studies was made in accordance with FIFRA guidelines and fits EPA criteria for waiving the tests.

Her recommendation, which has thus far been accepted, was that the test not be run due to the low pH (1.5) of Virkon S...the low pH was determined by slurrying Virkon S powder with a few drops of water, as would be done in the exposure phase of the tests.

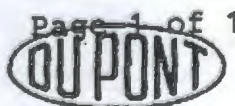
The concentration of such a slurry would be many orders of magnitude higher than use concentration, and much higher than concentrations likely to be experienced at any point in the use of the product. However, the dermal and eye tests require such concentrations, so the toxicologist had no choice but to make the slurry. Exposure to the dry powder Virkon S would not necessarily result in as low a pH as the test conditions unless the exposed area happened to be dampened with a very small amount of water at the time. Exposure to the diluted solution of Virkon S at recommended concentrations of 0.4-1.0% results in pH 3.5-4.0, which is much higher than is addressed by the Guidelines.

Best regards,



Bruce A. Evans  
Senior Technical Consultant

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PRINTED IN

From: FINLAYC --HSKVAX  
To: EVANSBA --ISCDCVM5

Date and time 04/17/95 10:58:23

From: FINLAYC --HSKVAX A1::FINLAYC  
Subj: Acute Studies with Virkon S

From: NAME: Carol Finlay  
FUNC: CR&D  
TEL: 366-5201 <FINLAYC AT A1 AT HSKVAX>  
To: NAME: Bruce A. Evans <EVANSBA AT ISCDCVM5>  
CC: NAME: KAVSY D DASTUR <DASTURKD AT A1 AT CSOC>,  
NAME: CHARLES F REINHARDT <REINHACF AT A1 AT HSKVAX>,  
NAME: HENRY J TROCHIMOWICZ <HJTROCH AT A1 AT HSKVAX>,  
NAME: NANCY C CHROMEY <CHROMEY AT A1 AT HSKVAX>

Author: Carol Finlay  
Date: 24-Oct-1989  
Revised-date: 17-Apr-1995

CENTRAL RESEARCH AND DEVELOPMENT  
HASKELL LABORATORY FOR TOXICOLOGY  
AND INDUSTRIAL MEDICINE

April 17, 1995

From: Carol Finlay

The EPA FIFRA testing guidelines (Subdivision F) state that substances with a demonstrated pH of 2 or less or 11.5 or greater need not be tested for primary dermal or eye irritation, owing to their predictable corrosive properties. The pH of Virkon S was determined to be 1.5. Additionally, as described in 40CFR ' 158.45, this fits the criteria the Agency considers when granting a waiver for Primary Dermal Irritation, Primary Eye Irritation, and Acute Dermal Toxicity studies. Therefore, I recommend that the Primary Dermal Irritation Study, Primary Eye Irritation Study, and Acute Dermal Toxicity Study with Virkon S not be conducted.

to: CDCIL1::ISCDCVM5::EVANSBA



## ACUTE TOXICITY TESTS ON VIRKON® S

EYE IRRITATION (RABBIT)  
SKIN IRRITATION (RABBIT)  
SKIN ABSORPTION LD50 (RABBIT)

EPA GUIDELINES RECOMMEND THAT NO TESTS BE RUN FOR SUBSTANCES WITH A pH OF  $\leq 2.0$ . SINCE THE SLURRIED VIRKON S POWDER HAS A pH OF 1.5, TESTS WERE NOT CONDUCTED FOR HUMANE REASONS.

### INHALATION LC50 (RAT)

THE 4-HOUR INHALATION LC50 WAS REPORTED AS 3.7 mg/L IN MALE AND FEMALE RATS; THE EEC CLASSIFICATION IS "HARMFUL".

THE INHALATION STUDY COULD NOT BE RUN ON THE COMMERCIAL PRODUCT BECAUSE IT DOES NOT CONTAIN ENOUGH RESPIRABLE PARTICLES TO ACHIEVE THE REQUIRED EXPOSURE LEVELS. GRINDING WAS DONE TO GENERATE THE RESPIRABLE PARTICLES NEEDED.

ACTIVE OXYGEN ANALYSES	% A. O.
CERTIFICATE OF ANALYSIS	= 2.28 [10.03 % A. Cl. * (8 / 35.5)]
IMMEDIATELY AFTER GRINDING	= 2.23
GROUND MATERIAL AFTER 8 WEEKS	= 0.533
UNGROUND MATERIAL AFTER 8 WEEKS	= 2.10

### CONCLUSIONS:

- THE COMMERCIAL PRODUCT VIRKON® S IS STABLE.
- THE ACTIVE OXYGEN CONTENT OF VIRKON® S WAS NOT LOWERED BY GRINDING.
- AFTER GRINDING, VIRKON® S WAS CONSIDERABLY LESS STABLE; THE CAUSE OF INSTABILITY IS NOT KNOWN, BUT IS BELIEVED TO BE RELATED TO ENHANCED MOISTURE PICKUP DUE TO ENLARGED SURFACE AREA.

### ACUTE ORAL TOXICITY (RAT)

THE COMBINED ORAL LD50 IS 4123 mg/kg IN MALE AND FEMALE RATS, AND IS CONSIDERED SLIGHTLY TOXIC.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

March 6, 2003

Mr. Jeff Jones  
Delta Analytical Corp., Agent for  
*Antec International Ltd.*  
7910 Woodmont Avenue, Suite 1000  
Bethesda, MD 20814

Subject: Label Amendment  
*Virkon S*  
EPA File Symbol Number 62432-1  
Application Dated November 26, 2002

Dear Mr. Jones:

The following amendments, submitted in connection with registration under section of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable with comments listed below:

Proposed Amendment

- To add additional pests to label
- Label changes per EPA letter dated September 17, 2002

Label Comments

The following label revisions must be made:

1. The following are considered to be "Public Health" microorganisms, therefore, without acceptable efficacy data, they must be deleted from the label.

- *Bacillus subtilis*
- *Listeria monocytogenes*
- Avian Infectious Bronchitis virus



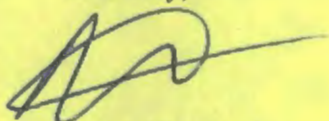
2. On page 1, delete the use in "Food Processing, including food handling and food preparation areas of restaurants and food processing plants."
3. On page 9, delete the heading "Food Processing" so that it reads "Institutional and Service Facilities (Human Health)."
4. On page 10, in the Storage and Disposal section, correct the spelling of the word "other".
5. In case of an emergency a telephone number (toll free if available) should be listed near the first aid statement.
6. Since this is a master labeling, add the word "MASTER LABEL" to the label.

**Other Comment:**

A stamped copy of the label is enclosed for your records. Submit three (3) copies of the revised final printed label before distributing or selling this product.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,



Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

Enclosure

## Virkon® S BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities (OPT.) OPT.  
Indicates marked language is optional.

Effective against Viruses  
(including CANINE PARVOVIRUS) • Bacteria • Fungi

For Use in Emergency Disease Control (OPT.)

For use in Cleaning and Disinfecting Institutional, Food Processing, and Service Facilities including food handling and food preparation areas of restaurants and food processing plants, stores, factories, schools, hotels, offices, ships, planes, transportation terminals, supermarkets and food warehouses. (OPT.)

For Use in Emergency Response and On-site Cleanup (emergency response calls, crime scenes, traffic accidents, fires, flood, natural and other disasters) e.g. cars, trucks, ambulances, and similar emergency apparatus, tires, wheels, floors, walls, ceilings, paved surfaces; and equipment such as SCBA, coats, boots, hats, masks, gloves, axes, Jaws of Life and similar emergency equipment. (OPT.)

For Use in Greenhouses, Horticulture, and Aquaculture (OPT.)

### ACTIVE INGREDIENTS:

Potassium peroxymonosulfate.....	20.4%
Sodium Chloride.....	1.5%
OTHER INGREDIENTS.....	<u>78.1%</u>
TOTAL.....	100.00%

Equivalent to 9.75% Available Chlorine

**ACCEPTED  
with COMMENTS**  
EPA Letter Dated:  
MAR - 6 2003

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 62432-1

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

See [Back] [Side] Panel[s] [Inside Booklet] for Additional Precautions



## Front Panel Continued

**FIRST AID**

**Have the product container or label with you when calling a poison control center or doctor, or going for treatment.**

**If Swallowed:**

- Call Poison Control Center or doctor immediately for treatment advice.
- Have Person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor
- Do not give anything by mouth to an unconscious person

**If Inhaled:**

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a Poison Control Center or doctor for further treatment advice.

**If in Eyes:**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present after 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for further treatment advice.

**If on Skin:**

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center or doctor for further treatment advice.

**Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage.

\_\_\_ lbs. (\_\_\_) Net Weight

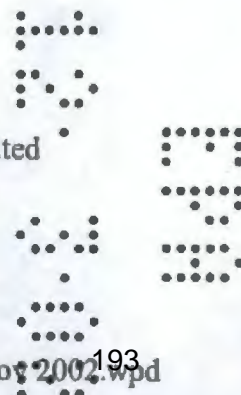
EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

**Antec**  
**International**  
LEADERS IN BIOSECURITY

**Manufactured By:**  
**ANTEC INTERNATIONAL LTD.**  
Windham Road, Chilton Industrial Estates  
Sudbury Suffolk CO10 6XD, England

Virkon<sup>®</sup> S is a registered trademark of and manufactured by Antec International Limited  
US Patent No. 4822512



[Comment: The list of claims (sites) under "EFFECTIVE AGAINST" may be placed in any order as long as each subheading and its contents remains intact.]

## EFFECTIVE AGAINST THE FOLLOWING ANIMAL HEALTH PATHOGENS:

### ANIMAL AND ZOONOTIC PATHOGENS

#### BACTERIA

Actinobacillus pleuropneumonia  
 Bacillus cereus  
 Bacillus subtilis  
 Bordetella avium  
 Bordetella bronchiseptica  
 Campylobacter pyloridis  
 Clostridium perfringens  
 Dermatophilus congolensis  
 Escherichia coli  
 Erysipelothrix rhusiopathiae  
 Fistulous withers (Poll Evil)  
 Haemophilus somnus  
 Klebsiella pneumoniae  
 Listeria monocytogenes  
 Moraxella bovis (Pink Eye)  
 Mycobacterium bovis  
 Mycoplasma gallisepticum  
 Mycoplasma mycoides  
 Pasteurella multocida  
 Pseudomonas aeruginosa  
 Pseudomonas mallei (Glanders)  
 Pseudomonas vulgaris  
 Salmonella choleraesuis  
 Salmonella typhimurium  
 Staphylococcus aureus  
 Staphylococcus epidermidis  
 Streptococcus equi (Strangles)  
 Streptococcus pyogenes  
 Streptococcus suis  
 Taylorella equigenitalis  
 Treponema hyodysenteriae

#### VIRUSES

Adenovirus Pneumonia  
 African Horse Sickness Virus  
 African Swine Fever Virus  
 Avian Infectious Bronchitis Virus  
 Avian Influenza Virus  
 Avian Laryngotracheitis Virus  
 Bovine Adenovirus Type 4  
 Bovine Polyoma Virus  
 Bovine Pseudocowpox Virus  
 Bovine Viral Diarrhea Virus  
 Calf Rotavirus  
 Canine Adenovirus  
 Canine Coronavirus  
 Canine Parainfluenza Virus  
 Canine Parvovirus  
 Chicken Anemia Virus  
 Coital Exanthema Virus  
 Distemper Virus  
 Duck Adenovirus  
 Duck Enteritis Virus  
 Egg Drop Syndrome Adenovirus  
 Equine Infectious Anemia Virus (Swamp Fever)  
 Equine Arteritis Virus  
 Equine Herpes Virus (Type 1)  
 Herpes Virus Equine (Type 3)  
 Hog Cholera Virus  
 Equine Contagious Abortion Virus  
 Equine Papillomatosis Virus  
 Equine Influenza Virus (Type A)  
 Equine Influenza Virus (The Cough)  
 Feline Calicivirus  
 Feline Herpes Virus  
 Feline Infectious Peritonitis Virus  
 Feline Panleukopenia Virus  
 Feline Parvovirus



## Feline Rhinotracheitis Virus

Foot and Mouth Disease Virus

Organism

Infectious Bronchitis Virus

Infectious Bursal Disease Virus

Infectious Canine Hepatitis Virus

Infectious Pancreatic Necrosis Virus

Infectious Salmon Anaemia Virus

Infective Bovine Rhinotracheitis Virus

Leptospira Canicola Virus

Maedi-Visna Virus

Marek's Disease Virus

Newcastle Disease Virus

PCV2 Virus (PMWS)

Porcine Parvovirus

Porcine Reproductive and Respiratory  
Syndrome Virus (PRRS)

Pseudorabies Virus (Aujeszky's Disease)

Rotaviral Diarrhea Virus

Snakehead rhabdovirus

SV40 Virus

Swine Influenza Virus

Transmissible Gastroenteritis Virus (TGE)

Turkey Herpes Virus

Turkey Rhinotracheitis Virus

Vesicular Stomatitis Virus

## PLANT PATHOGENS

Alternaria solani

Botrytis cinera

Colletotrichum coccodes

Didymella bryoniae

Fusarium oxysporum

Fusarium solani

Penicillium oxalicum

Phomopsis sclerotoides

Pyrenochaeta lycoopersici

Pythium aphanidermatum

Rhizoctonia solani

Sclerotinia sclerotiorum

Thielaviopsis basicola

Verticillium dahliae

## FUNGI

Aspergillus fumigatus

Candida albicans

Fusarium moniliforme

Microsporum canis

Trichophyton spp. (Ringworm)

Trichophyton spp. (Mud Fever)

## EFFECTIVE AGAINST THE FOLLOWING HUMAN HEALTH PATHOGENS:

Human Immuno-Deficiency Virus (HIV) Type 1 (on hard non-porous surfaces), Streptococcus pyogenes, Campylobacter pyloridis, klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, and Candida albicans.



**PRECAUTIONARY STATEMENTS****HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER.** Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. **Corrosive statement refers to powder only not in use solution.**

[Comment: The instructions under "DIRECTIONS FOR USE" may be placed in any order as long as they remain a continuous section on the label.]

**BROAD SPECTRUM DISINFECTANT**

Virkon<sup>®</sup> S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy of the 1% solution was determined in the presence of 400 ppm AOAC hard water and 5% organic material. Virkon<sup>®</sup> S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water. Apply a 0.5% (1:200) solution for routine sanitation.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

**GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES**

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.
  2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.
  3. Empty all troughs, racks, and other feeding and watering appliances.
  4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
  5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
  6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
  7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.
  8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.
- This powder formula is easily diluted for use in manual or machine operations.



**Virkon® S DILUTION CHART**

Fill container with desired amount of water and add Virkon® S powder to achieve recommended solution concentration.

Quantity of Water	0.5% Solution	1% Solution	2% Solution
1 Quart	0.15 ounces	0.3 ounces	0.7 ounces
1 Gallon	0.65 ounces	1.3 ounces	2.7 ounces
10 Gallons	6.7 ounces	13.4 ounces	26.7 ounces
50 Gallons	33.4 ounces	66.8 ounces	133.5 ounces

Measuring cup provided.

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

### POULTRY [PRODUCTION] [AND RATITE PRODUCTION]

[CONTROLS: Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*. Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium* and *Mycoplasma gallisepticum*.] (OPT.)

HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*).

Virkon® S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: Use Virkon® S at 0.5-1% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use. PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors.



## SWINE PRODUCTION

[CONTROLS: Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine Fever and Foot and Mouth Disease. Bacteria of Pleuropneumonia, *Treponema hyodysenteriae*, and *Clostridium perfringens*. Fungi: *Fusarium moniliforme*.] (OPT.)

Follow General Instructions to remove swine and pre-clean area to be treated. Virkon® S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants (use a 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*), and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

## EQUINE PRODUCTION

## BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

[CONTROLS: Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis. Bacterial: *Clostridial* Diarrhea, Fistulous Withers (Poll Evil), *Taylorella equigenitalis*, *Bordetella bronchiseptica*, *Streptococcus equi* (Strangles) and *Pseudomonas mallei* (Glanders). Fungi: *Dermatophytosis* (Ringworm), *Dermatophylosis* (Mud Fever), and *Fusarium moniliforme*.] (OPT.)

APPLICATIONS: For cleaning and disinfecting all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

## USES:

Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution. Rinse with clean water.

Blankets, Saddle Pads and Rugs: Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

Aerial Spraying to control airborne diseases: Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon® S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.



## BOVINE PRODUCTION

[CONTROLS: Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies and Foot and Mouth Disease; Bacteria of *Maraxella bovis*, *Haemophilus somnus* and *Mycobacterium bovis*; Fungi of *Fusarium moniliforme*.] (OPT.)

Follow General Instructions to remove livestock and preclean area to be treated. A 1% solution of Virkon® S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

## COMPANION ANIMALS

[CONTROLS: Viruses Canine Parvovirus, Distemper, *Leptospira canicola*, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of *Staphylococcus aureus*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*; Fungi of *Microsporum canis*.] (OPT.)

[APPLICATIONS] A 1% solution of Virkon® S is recommended as a "one step" cleaning and disinfecting procedure for all surfaces, equipment, instruments, utensils and cages [caging systems] within [associated with] Veterinary Medical Hospitals, infectious disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

## GREENHOUSES AND HORTICULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces, glasshouse structures, equipment, utensils, trays, containers, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

Remove all crop debris, strings and other deposits from structures, empty trays and pots. Power wash all the dust off the covering and superstructure and let dry. Using a sprayer or fogger saturate all surfaces with a 1% solution of Virkon® S. Let air dry.

Virkon® S may also be used to disinfect irrigation tanks and lines. Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon® S at 0.5-1%% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.



## AQUACULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

## EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

**CONTROLS:** OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus. (OPT.)

A 1% solution of Virkon® S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

INSTITUTIONAL, FOOD PROCESSING, AND SERVICE FACILITIES  
(HUMAN HEALTH)

**CONTROLS:** Human Immuno-Deficiency Virus (HIV) Type 1 (on hard non-porous surfaces), Streptococcus pyogenes, Campylobacter pyloridis, klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, and Candida albicans. (OPT.)



With Virkon® S, only one product is needed to clean and disinfect all surfaces except acid-sensitive surfaces such as copper, brass, or aluminum. Do not use Virkon S on these acid-sensitive surfaces. Avoid splashing Virkon® S solution on textiles or carpets. Virkon® S may be used on carpeting or other textiles only if area is tested for color fastness before use and treated area vacuumed when dry.

**Cleaning and Disinfecting Food-Contact Surfaces:** Remove gross dirt and prepare 1.0% solution according to the Dilution Chart. Apply to surface using a sponge, brush, or spray device until the surface is visibly clean. Let stand for 10 minutes and rinse with potable water.

**Cleaning and Disinfecting Non-Food Contact Surfaces:** Remove gross dirt and use 1.0% Virkon® S solution prepared according to the Dilution Chart below. Apply to surface using a mop, sponge, brushes or spray device until the surface is visibly clean. Air dry. In cases of fungal or viral contamination of non-food contact surfaces, follow these instructions substituting a 2.0% Virkon® S solution.

**Sanitizing Toilet Bowls.** After flushing, sprinkle 1 oz. Virkon® S powder around the bowl, scrub with a brush, and leave for 10 minutes. Flush.

**Cleaning and Disinfecting Manikins Used in CPR Training:** Manikins should be cleaned as soon as possible at the end of each class to avoid drying of contaminants on surfaces. Disassemble the manikin as directed by the manufacturer's instructions. Thoroughly wash all internal and external surfaces and reusable protective face shields with a brush using a 1% Virkon® S solution. Let stand for 10 minutes and rinse with potable water.

**Cleaning and Disinfecting Hard, Non-porous Surfaces Suspected of HIV Type 1 Contamination:** Cover heavy spillage of body fluids with Virkon® S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste. Prepare 2% Virkon® S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

#### EMERGENCY RESPONSE AND ON-SITE CLEANUP

Cover heavy spillage of body fluids with Virkon® S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste.

Prepare 2% Virkon® S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

#### STORAGE AND DISPOSAL

**STORAGE:** Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

**DISPOSAL:** Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals.



**Renae Whitaker**

12/18/02 02:51 PM

To: Emily Mitchell/DC/USEPA/US@EPA

cc:

Subject: Virkon S; EPA Reg. No. 62432-1; Notification/amendment

Emily this if FYI

----- Forwarded by Renae Whitaker/DC/USEPA/US on 12/18/02 02:50 PM -----



**Jeff Jones**

**<jjones@delta-ac.com**

**>**

12/18/02 02:25 PM

To: Renae Whitaker/DC/USEPA/US@EPA

cc: Adam Heyward/DC/USEPA/US@EPA

Subject: Virkon S; EPA Reg. No. 62432-1; Notification/amendment

Renae:

Thanks for your call this morning. I understand that you've decided to treat our recent filing as a minor amendment rather than a notification.

Since I made the filing I have reviewed PR Notice 2002-1 and note that the Agency classifies two bacteria I proposed to add to the label, *bacillus cereus* and *erysipelothrix rhusiopathiae*, as public health pests. Accordingly, I am prepared to remove those organisms from our proposed label. Let me know if you would like me to submit a revised label making those changes.

Thanks for your assistance.

Best regards,

Jeff Jones

Delta Analytical Corporation

7910 Woodmont Ave. Suite 1000

Bethesda, MD 20814

[jjones@delta-ac.com](mailto:jjones@delta-ac.com)

301 652 5495

301 652 5408 Fax





November 26, 2002

Mr. Adam Heyward, PM #34  
Antimicrobials Branch  
US EPA  
Washington, DC 20460

Subject: Virkon S; EPA Reg. No. 62432-1; Notification of Additional Pests and Label Changes in Response to Agency Letter Dated 17 September 2002

Dear Adam:

Enclosed please find the following documents pursuant to a notification of additional pests and label changes in response to Agency letter dated 17 September 2002:

- Application for Pesticide Registration (EPA Form 8570-1)
- Proposed Product Label (5 copies with proposed changes highlighted)
- Current Stamped Label
- Agency Letter Dated 17 September 2002

You will note that in addition to proposing new pests (highlighted) to add to the label, I have reformatted the list of pests removing the categories bovine, swine, poultry, etc. and placing the listed pests in alphabetical order. As required by PR Notice 98-10, to the best of my knowledge none of the added pests are a threat to public health pests or subject to quarantine by APHIS.

The proposed label also has been modified as you requested in your letter of September 17, 2002 as discussed below.

Comment #1: The label has been modified to include a reference to HIV Type 1 and that efficacy was demonstrated on hard non-porous surfaces.

Comment #2: The label has been modified to make clear that Virkon is effective on all surfaces except acid-sensitive surfaces.

Comment #3: Specific microorganisms are listed in the section discussing the animal, zoonotic, and plant pathogens against which Virkon S is effective.

Comment #4: The levels of hard water (400 ppm AOAC hard water) and organic material (5%) have been added to the label.

Comment #5: Instructions for treating surfaces suspected of HIV contamination have been added in the Institutional and Service Facilities (Human Health) section of the label drawing from previously approved language in the Emergency Response and On-site Cleanup section.

Comment #6: As the label now explains those sections marked "(OPT.)" are optional and may be included on marketplace labels at Antec's discretion.

Comment #7: The directions for cleaning and disinfecting food contact surfaces have been removed.

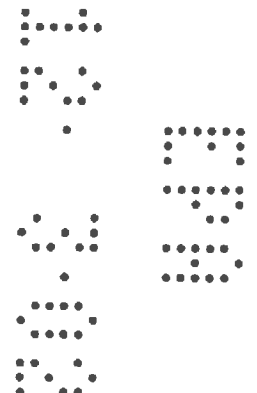
Comment #8: The directions call for flushing the toilet before adding Virkon S and take into account the amount of water in the bowl in determining the appropriate dilution factor.

Let me know if you have any questions regarding this submission or if I need to supply additional information. Thanks for your assistance.

Sincerely,



T. Jeffrey Jones, Agent  
Antec International Ltd.  
Enclosures







United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

231295

## Application for Pesticide - Section I

1. Company/Product Number 62432-1	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Virkon S	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd. c/o Delta Analytical Corp. 7910 Woodmont Ave., Suite 1000 Bethesda, MD 20814  <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. _____  Product Name _____

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Notification:** Use additional page(s) if necessary. (For section I and Section II.)

Notification of addition of pests and label changes requested in Agency letter dated September 17, 2002. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 USC Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

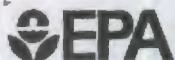
## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Jeff Jones		Title Agent, Antec International Ltd.		Telephone No. (include Area Code) 301 652 5495	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped) 
2. Signature 		3. Title Agent, Antec International Ltd.			
4. Typed Name Jeff Jones		5. Date 26 November 2002			





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

231295

## Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code)  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name		Title		Telephone No. (Include Area Code)	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped) 
2. Signature		3. Title			
4. Typed Name		5. Date			



## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

**Submission of Labeling** - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data** - Data submitted in support of this application must be submitted in accordance with PR Notice 88-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A** - Check the appropriate action for which you are submitting this form.

**SECTION I** - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II** - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III** (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which Labels are affixed to product** - Indicate the method product label is attached to retail container.

**SECTION IV** (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me too" reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



SUBMISSION BAR CODE # 3 6276 87REVIEWER M TerryCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 62432-1 PM 33 ACTION CODE 400DESCRIPTOR Support Data

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION  
 [ ] NON-RESIDENTIAL USE ONLY  
 [ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

12 23 0201 02 0301 06 03~~METHOD OF SUPPORT~~~~FORMULATORS EXEMPTION~~

[ ] CITE ALL  
 [ ] SELECTIVE  
 [ ] NOT SUBMITTED  
 [ ] NOT APPLICABLE  
 [ ] INCORRECT/RESUB

[ ] SUBMITTED  
 [ ] NOT SUBMITTED  
 [ ] NOT APPLICABLE  
 [ ] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA  
PACK #DATE  
SENTDUE  
DATEDATE  
RETURNS

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

RESPONSE CODE

38

RESPONSE DATE

1/13/03



pm 33

**degussa.**

Management Services

**Degussa Corporation**

379 Interpace Parkway  
P.O. Box 677  
Parsippany, NJ 07054-0677

Direct: 973-541-8047  
Fax: 973-541-8040  
Shaun.Clancy@degussa.com  
www.degussa.com

December 23, 2002

Registration Division (H7504C)  
Office of Pesticide Programs  
US EPA  
Washington, DC 20460

re: Permission to Cite Degussa Data

Dear Sir or Madam:

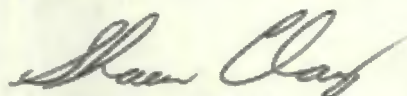
Degussa Corporation authorizes the Agency to refer to the data cited below in support of registration of products containing the active ingredients, hydrogen peroxide and peroxyacetic acid, by Antec International Limited (Company Number 62432). Antec will shortly submit an application for registration for its product, HyperOx, citing this data.

MRID Number	Reference
44506501	Degussa Corp. (1998) Product Chemistry Peraclean 5% (Peroxyacetic Acid Solution): Lab Project Number: AOC002. Unpublished study. 36 p.

Degussa Corporation hereby waives the 30-day notification period prior to registration of this application as provided in 40 CFR 152.116(c)

If you have any questions regarding this matter, please contact the undersigned at 973-541-8047.

Sincerely,



Shaun Clancy, Ph.D  
Director, Product Regulatory Services

cc: Bob Gec

1/2/03





United States  
Environmental Protection Agency  
Office of Pesticide Programs (7505C)  
Washington, DC 20460

40A 2-2  
287342

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product

62432-1

Distributor Company Number

003134

Note: Do not submit distributor product labels

Name of Registered Product (basic product name accepted by EPA)

Markon-S

Distributor Product Name

Trifectant Broad Spectrum Disinfectant

Name and Address of Distributor (Type; include ZIP code)

Logoquint USA Inc.  
11 Lincoln Ave.  
Buena New Jersey 08310  
1-800-267-5707

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

ERIC J. LINN DVM, MPH  
Director Regulatory Compliance

Date  
9/16/02

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

(MANAGING DIRECTOR)

Date  
10/09/2002

11.8.2002



## CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO.

62432-1

PM

34

ACTION CODE

307

DESCRIPTOR

Label updated w/ supporting efficacy data

☐ CHILD RESISTANT PACKAGING:☐

CERTIFICATION

☐

NON-RESIDENTIAL USE ONLY

☐

NOT APPLICABLE

REGISTRATION TYPE:

☐

CONDITIONAL

☐

UNCONDITIONAL

PROPOSED CLASSIFICATION:

☐

GENERAL

☐

RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

3 22 2002

3 25 02

4 1 02

METHOD OF SUPPORT

FORMULATORS' EXEMPTION

☐

CITE-ALL

☐

SELECTIVE

☐

NOT SUBMITTED

☐

NOT APPLICABLE

☐

INCORRECT/RESUB

☐

SUBMITTED

☐

NOT SUBMITTED

☐

NOT APPLICABLE

☐

INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA

DATE

DUE

DATE

PACK #

SENT

DATE

RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

RESPONSE CODE

17

RESPONSE DATE

SEP 17 2002





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

SEP 17 2002

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Mr. Jeff Jones  
Delta Analytical Corporation, Agent for  
Antec International Ltd.  
7910 Woodmont Avenue, Suite 1000  
Bethesda, MD 20814

Subject: **Virkon S**  
EPA Registration No.62432-1  
Amended Application Dated March 21, 2002

Dear Mr. Jones:

The amendments referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable with the following comments.

**Proposed Amendments:**

- Add Greenhouse, Horticulture Uses, and Aquaculture Uses
- Add Emergency Response and On-site Cleanup Uses
- Add HIV claim
- Update First Aid language

**Efficacy Comments**

The submitted efficacy data (MRID 456371-01) is acceptable to support the use of a 1% solution of the product, Virkon S as a virucide when tested against HIV type 1 virus, in the presence of 400ppm hard water and a 5% organic soil load (fetal bovine serum) on hard, non-porous surfaces for a contact time of 10 minutes. Cytotoxicity was observed at the  $10^{-2}$  dilution. Complete inactivation (no growth) was indicated in the  $10^{-3}$  through  $10^{-7}$  dilutions. A 4-log reduction beyond the cytotoxic level was evident.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

212



**Label Comments:**Nonacceptable Labeling:

1. The proposed label claims (as supported by MRID 456371-01) are not currently acceptable regarding the use of the product as a disinfectant against "Human Immuno-Deficiency Virus (HIV)" for a contact time of 10 minutes (or until air-dried). The proposed label needs to clearly indicate that efficacy relates specifically to HIV type 1. In addition, the proposed label needs to clearly indicate that efficacy relates to hard, non-porous surfaces.
2. Text on page 9 of the proposed label states: "With Virkon S, only one product is needed to clean and disinfect all surfaces." This language must be deleted. The statement "Do Not Use Virkon® S on acid-sensitive surfaces such as marble or soft metals such as copper, brass, or aluminum" would make the above statement mute.
3. No specific microorganisms are listed; there is no asterisk (\*) to a list of organisms elsewhere. However, the proposed and last accepted labels do include lists of animal health pathogens and human health pathogens.
4. The levels of hard water and organic material are not indicated on label.
5. Although disinfection use directions were provided, the proposed label did not include special instructions for cleaning and decontaminating against HIV-1 on pre-cleaned surfaces or objects soiled with blood/body fluids. Appropriate instructions for cleaning and decontamination must be provided on the label.
6. Respect to statement "For Use in Emergency Disease Control (OPT), see EPA letter dated August 1, 2002, comments 1 and 2.
7. On page 9, delete the directions for cleaning and disinfecting food contact surfaces.
8. On page 9, under sanitizing toilet bowls the label must state that the bowl must be emptied before adding product. Dilution factor must take in to account of water in the toilet bowl.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							



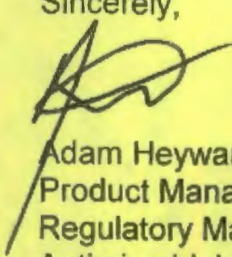
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

General Comments:

For detailed considerations, refer to the enclosed EPA/AD Product Science Branch efficacy review dated September 3, 2002. Submit three (3) copies of your revised printed label bearing the revisions stated above for review.

If you have any questions concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,

  
Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								



## Virkon® S

### BROAD SPECTRUM DISINFECTANT

**For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities (OPT.)**

**For Use in Emergency Disease Control (OPT.)**

**For use in Cleaning and Disinfecting Institutional, Food Processing, and Service Facilities including food handling and food preparation areas of restaurants and food processing plants, stores, factories, schools, hotels, offices, ships, planes, transportation terminals, supermarkets and food warehouses. (OPT.)**

**For Use in Emergency Response and On-site Cleanup (emergency response calls, crime scenes, traffic accidents, fires, flood, natural and other disasters) e.g. cars, trucks, ambulances, and similar emergency apparatus, tires, wheels, floors, walls, ceilings, paved surfaces; and equipment such as SCBA, coats, boots, hats, masks, gloves, axes, Jaws of Life and similar emergency equipment (OPT.)**

**For Use in Greenhouses, Horticulture, and Aquaculture (OPT.)**

#### ACTIVE INGREDIENTS:

Potassium peroxymonosulfate.....	20.4%
Sodium Chloride.....	1.5%
INERT INGREDIENTS.....	78.1%
TOTAL.....	100.00%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

See Back [Side] Panel[s] for Additional Precautions

Front Panel Continued

**FIRST AID**

**Have the product container or label with you when calling a poison control center or doctor, or going for treatment.**

**If Swallowed:**

- Call Poison Control Center or doctor immediately for treatment advice.
- Have Person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor
- Do not give anything by mouth to an unconscious person

**If Inhaled:**

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a Poison Control Center or doctor for further treatment advice.

**If in Eyes:**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present after 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for further treatment advice.

**If on Skin:**

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center or doctor for further treatment advice.

**Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage.

\_\_\_ lbs. (\_\_\_) Net Weight

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

**ANTEC INTERNATIONAL LTD.**  
 Windham Road, Chilton Industrial Estates  
 Sudbury Suffolk CO10 6XD, England

Tel: (1787) 77305 Telex: 987495 Fax: (1787) 310846

Virkon<sup>®</sup> S is a registered trademark of and manufactured by Antec International Limited  
 US Patent No. 4822512



**EFFECTIVE AGAINST FOLLOWING ANIMAL HEALTH PATHOGENS:****EQUINE BACTERIA**

*Clostridium perfringens*  
 Fistulous withers (Poll Evil)  
*Taylorella equigenitalis*  
*Streptococcus equi* (Strangles)  
*Pseudomonas mallei*  
 (Glanders)  
*Bordetella bronchiseptica*

**EQUINE VIRUSES**

African Horse Sickness  
 Equine Viral Arteritis  
 (Pink Eye)  
 Coital Exanthema  
 Myeloencephalopathy  
 Rhinopneumonitis  
 Equine Infectious Anemia  
 (Swamp Fever)  
 Equine papillomatosis  
 Equine Contagious Abortion  
 Adenovirus Pneumonia  
 Equine Influenza (The Cough)

**EQUINE FUNGI**

*Trichophyton* spp.  
 (Ringworm)  
*Trichophyton* spp.  
 (Mud Fever)  
*Fusarium moniliforme*

**BOVINE BACTERIA**

*Moraxella bovis*  
*Mycobacterium bovis*  
*Haemophilus somnus*

**BOVINE VIRUSES**

Calf rotavirus  
 Infective Bovine  
 Rhinotracheitis

**Bovine Adenovirus Type 4**

Pseudorabies  
 Foot & Mouth Disease

**BOVINE FUNGI**

*Fusarium moniliforme*

**POULTRY BACTERIA**

*Streptococcus pyogenes*  
*Campylobacter pyloridis*  
*Klebsiella pneumoniae*  
*Escherichia coli*  
*Salmonella typhimurium*  
*Salmonella choleraesuis*  
*Pseudomonas aeruginosa*  
*Staphylococcus aureus*  
*Staphylococcus epidermidis*  
*Mycoplasma gallisepticum*  
*Clostridium perfringens*  
*Bordetella avium*

**POULTRY VIRUSES**

Newcastle Disease  
 Infectious Bronchitis  
 Infectious Bursal Disease  
 Avian Laryngotracheitis  
 Avian Influenza  
 Marek's Disease  
 Egg Drop Syndrome  
 Adenovirus  
 Turkey Herpes Virus  
 Duck Herpes Virus  
 Duck Viral Enteritis

**POULTRY FUNGI**

*Aspergillus flavus*  
*Aspergillus fumigatus*  
*Candida albicans*

**SWINE BACTERIA**

*Bordetella bronchiseptica*  
*Pasteurella multocida*  
*Actinobacillus*  
*pleuropneumonia*  
*Treponema hyodysenteriae*  
*Clostridium perfringens*  
**SWINE VIRUSES**  
 Hog Cholera  
 Swine Influenza  
 Porcine parvovirus  
 Rotaviral diarrhea  
 Vesicular stomatitis  
 Pseudorabies  
 Porcine Reproductive and  
 Respiratory Syndrome  
 (PRRS)  
 African Swine Fever  
 Foot and Mouth Disease

**SWINE FUNGI**

*Fusarium moniliforme*

**COMPANION ANIMALS****BACTERIA**

*Staphylococcus aureus*  
*Streptococcus pyogenes*  
*Klebsiella pneumoniae*  
*Pseudomonas aeruginosa*

**VIRUSES**

Canine Parvovirus  
 Distemper  
*Leptospira canicola*  
 Feline parvovirus  
 Feline herpes  
 Feline calicivirus

**FUNGI**

*Microsporum canis*

**EFFECTIVE AGAINST THE FOLLOWING HUMAN HEALTH PATHOGENS**

Human Immuno-Deficiency Virus (HIV), *Streptococcus pyogenes*, *Campylobacter pyloridis*, *klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Candida albicans*.



**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**  
**DANGER**

Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. **Corrosive statement refers to powder only not in use solution.**

**BROAD SPECTRUM DISINFECTANT**

Virkon<sup>®</sup> S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material. Virkon<sup>®</sup> S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water. **Apply a 0.5% (1:200) solution for routine sanitation.**

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

**GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES**

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.
2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.
8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

This powder formula is easily diluted for use in manual or machine operations.



**Virkon<sup>®</sup> S DILUTION CHART**

Fill container with desired amount of water and add Virkon<sup>®</sup> S powder to achieve recommended solution concentration.

Quantity of Water	Amount of Powder for a 0.5% Solution	Amount of Powder for 1% Solution	Amount of Powder for 2% Solution
1 Quart	0.15 ounces	0.3 ounces	0.7 ounces
1 Gallon	0.65 ounces	1.3 ounces	2.7 ounces
10 Gallons	6.7 ounces	13.4 ounces	26.7 ounces
50 Gallons	33.4 ounces	66.8 ounces	133.5 ounces

1.3 oz. measuring scoop is provided. Measuring cup provided.

Add [1.3 oz. (1 scoop) of Virkon<sup>®</sup> S [the contents of one Virkon<sup>®</sup> S packet] to one gallon of warm water. Solutions are stable for 7 days. Do not soak metal objects in Virkon<sup>®</sup> S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

### POULTRY AND RATITE PRODUCTION

**CONTROLS:** Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*. Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium* and *Mycoplasma gallisepticum*.

**HATCHERIES:** Virkon<sup>®</sup> S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*).

Virkon<sup>®</sup> S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

**BROILER/BREEDER HOUSES:** Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon<sup>®</sup> S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon<sup>®</sup> S (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

**FOR AIR SANITIZING:** Use Virkon<sup>®</sup> S at 0.5-1% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

**PROCESSING PLANTS:** Spray Virkon<sup>®</sup> S at 1% solution to disinfect and clean walls, ceilings and floors.



## SWINE PRODUCTION

**CONTROLS:** Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine Fever and Foot and Mouth Disease. Bacteria of Pleuropneumonia, Treponema hyodysenteriae, and Clostridium perfringens. Fungi: Fusarium moniliforme.

Follow General Instructions to remove swine and preclean area to be treated. Virkon<sub>®</sub> S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants (use a 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus), and agricultural production equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon<sub>®</sub> S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

## EQUINE PRODUCTION

### BROAD SPECTRUM EQUINE DISINFECTANT/DETERGANT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

**CONTROLS:** Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis. Bacterial: Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders). Fungi: Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), and Fusarium moniliforme.

**APPLICATIONS:** For cleaning and disinfecting all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

#### USES:

**Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms:** Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon<sub>®</sub> S solution. Rinse with clean water.

**Blankets, Saddle Pads and Rugs:** Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

**Aerial Spraying to control airborne diseases:** Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon<sub>®</sub> S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.



## BOVINE PRODUCTION

**CONTROLS:** Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies and Foot and Mouth Disease; Bacteria of *Maraxella bovis*, *Haemophilus somnus* and *Mycobacterium bovis*; Fungi of *Fusarium moniliforme*.

Follow General Instructions to remove livestock and preclean area to be treated. A 1% solution of Virkon<sup>®</sup> S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

## COMPANION ANIMALS

**CONTROLS:** Viruses Canine Parvovirus, Distemper, *Leptospira canicola*, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of *Staphylococcus aureus*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*; Fungi of *Microsporum canis*.

A 1% solution of Virkon<sup>®</sup> S is recommended as a "one step" cleaning and disinfecting procedure for all surfaces, equipment, instruments, utensils and cages [caging systems] within [associated with] Veterinary Medical Hospitals, infectious disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon<sup>®</sup> S for long periods - 10 minutes is maximum contact time.

## GREENHOUSES AND HORTICULTURE

Virkon<sup>®</sup> S is intended to disinfect inanimate environmental surfaces, glasshouse structures, equipment, utensils, trays, containers, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

Remove all crop debris, strings and other deposits from structures, empty trays and pots. Power wash all the dust off the covering and superstructure and let dry. Using a sprayer or fogger saturate all surfaces with a 1% solution of Virkon<sup>®</sup> S. Let air dry.

Virkon<sup>®</sup> S may also be used to disinfect irrigation tanks and lines. Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon<sup>®</sup> S at 0.5-1%% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog



(wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

## AQUACULTURE

Virkon<sub>S</sub> is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon<sub>S</sub> may also be used in foot dips. Virkon<sub>S</sub> must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon<sub>S</sub> solution followed by a water rinse.

Virkon<sub>S</sub> at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

## EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

**CONTROLS:** OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus.

A 1% solution of Virkon<sub>S</sub> is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray Virkon<sub>S</sub> at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon<sub>S</sub> for long periods - 10 minutes is maximum contact time.



## INSTITUTIONAL, FOOD PROCESSING, AND SERVICE FACILITIES (HUMAN HEALTH)

**CONTROLS:** Human Immuno-Deficiency Virus (HIV), *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Candida albicans*.

With Virkon<sub>S</sub>, only one product is needed to clean and disinfect all surfaces.

Do Not Use Virkon<sub>S</sub> on acid-sensitive surfaces such as marble or soft metals such as copper, brass, or aluminum. Avoid splashing Virkon<sub>S</sub> solution on textiles or carpets. Virkon<sub>S</sub> may be used on carpeting or other textiles only if area is tested for color fastness before use and treated area vacuumed when dry.

**Cleaning and Disinfecting Food Contact Surfaces:** Remove gross dirt and prepare 1.0% solution according to the Dilution Chart. Apply to surface using a sponge, brush, or spray device until the surface is visibly clean. Let stand for 10 minutes and rinse with potable water.

**Cleaning and Disinfecting Non-Food Contact Surfaces:** Remove gross dirt and use 1.0% Virkon<sub>S</sub> solution prepared according to the Dilution Chart below. Apply to surface using a mop, sponge, brushes or spray device until the surface is visibly clean. Air dry. In cases of fungal or viral contamination of non-food contact surfaces, follow these instructions substituting a 2.0% Virkon<sub>S</sub> solution.

**Sanitizing Toilet Bowls.** After flushing, sprinkle 1 oz. Virkon<sub>S</sub> powder around the bowl, scrub with a brush, and leave for 10 minutes. Flush.

**Cleaning and Disinfecting Manikins Used in CPR Training:** Manikins should be cleaned as soon as possible at the end of each class to avoid drying of contaminants on surfaces. Disassemble the manikin as directed by the manufacturer's instructions. Thoroughly wash all internal and external surfaces and reusable protective face shields with a brush using a 1% Virkon<sub>S</sub> solution. Let stand for 10 minutes and rinse with potable water.

### EMERGENCY RESPONSE AND ON-SITE CLEANUP

Cover heavy spillage of body fluids with Virkon<sub>S</sub> powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste.

Prepare 2% Virkon<sub>S</sub> solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

### STORAGE AND DISPOSAL

**STORAGE:** Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

**DISPOSAL:** Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

September 3, 2002

**MEMORANDUM:**

**Subject:** Efficacy Review for EPA Reg. No. 62432-1, "Virkon® S"  
DP Barcode: D282057  
Case No: 001751

**From:** Emily Mitchell, M.S., Team Leader *Emily Mitchell 9/5/02*  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510C)

**Through:** Michele E. Wingfield, Chief  
Product Science Branch  
Antimicrobials Division (7510C)

**To:** Adam Heyward, PM 34/Renae Whitaker  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

**Applicant:** Antec International Ltd.  
Sudbury, Suffolk, England

**Formulation From Label:**

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Potassium peroxymonosulfate.....	20.4%
Sodium Chloride.....	1.5%
<u>Inert Ingredient(s)</u> .....	77.1%
Total .....	100.00%



## **I BACKGROUND:**

The product, Virkon S (EPA Reg. No. 062432-00001), is a disinfectant for use on hard, non-porous surfaces, including for use in emergency disease control. The applicant is amending the registration of this product to add claims for effectiveness against an additional virus, specifically HIV Type 1. The proposed label also includes additional uses previously approved for a similar product (i.e., Virkon, EPA Reg. No. 062432-00002). The study was conducted at ViroMed Laboratories, Inc., located at 6101 Blue Circle Drive, Minneapolis, Minnesota 55343.

This data package contained a copy of EPA Form 8570-1 (Application for Pesticide), one study (MRID No. 456371-01), a Statement of No Data Confidentiality Claims for the study, and the proposed label.

## **II USE DIRECTIONS:**

The product is to be used for disinfecting hard, non-porous surfaces in industrial, animal, and agricultural facilities and for use in emergency disease control. The label directions provide the following information regarding preparation and use of the product when used in institutional, food processing, and service facilities for human health:

"Cleaning and Disinfecting Food Contact Surfaces: Remove gross dirt and prepare a 1.0% solution according to the Dilution Chart. Apply to surface using a sponge, brush, or spray device until the surface is visibly clean. Let stand for 10 minutes and rinse with potable water.

Cleaning and Disinfecting Non-Food Contact Surfaces: Remove gross dirt and use a 1.0% Virkon S solution prepared according to the Dilution Chart below. Apply to surface using a mop, sponge, brushes or spray device until the surface is visibly clean. Air dry. In cases of fungal or viral contamination of non-food contact surfaces, follow these instructions substituting a 2.0% Virkon S solution.

Sanitizing Toilet Bowls: After flushing, sprinkle 1 oz. Virkon S powder around the bowl, scrub with a brush, and leave for 10 minutes. Flush.

Cleaning and Disinfecting Manikins Used in CPR Training: Manikins should be cleaned as soon as possible at the end of each class to avoid drying of contaminants on surfaces. Disassemble the manikin as directed by the manufacturer's instructions. Thoroughly wash all internal and external surfaces and reusable protective face shields with a brush using a 1% Virkon S solution. Let stand for 10 minutes and rinse with potable water.

Emergency Response and On-Site Cleanup: Cover heavy spillage of body fluids with Virkon S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste. Prepare 2% Virkon S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry."



The label directions do not include special instructions for cleaning and decontaminating against HIV-1 on pre-cleaned surfaces or objects soiled with blood/body fluids.

### **III AGENCY STANDARDS FOR PROPOSED CLAIMS:**

The Agency standards for virucidal claims are listed in DIS-TSS-7. The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products Test (for spray disinfectants) must be used in developing data for virucides intended for use upon dry inanimate, environmental surfaces (e.g., floors, tables, cleaned dried medical instruments). To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of two different batches of disinfectant must be tested against a recoverable virus titer of at least  $10^4$  from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

#### **Supplemental Claims**

An antimicrobial agent identified as a "one-step" cleaner-disinfectant, cleaner-sanitizer, or one intended to be effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. These Agency standards are presented in DIS/TSS-2.

The hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish disinfectant efficacy in hard water, all microorganisms (bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level. These Agency standards are also presented in DIS/TSS-2.

### **IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES:**

**MRID 456371-01 "10 Minute Inactivation of Human Immunodeficiency Virus Type 1 by Virkon S", by C. Sue Brady. Study completion date – September 21, 1995.**

The product was diluted 1:100 (50 grams test substance + 5 liters 400 ppm hard water). Actual hard water titration results were 404 ppm and 400 ppm hard water – separate batches of hard water were used to dilute the two batches of product. Two



lots (Lot Nos. 1698 and 2050) of the product were tested for a contact time of 10 minutes at room temperature against HIV-1, Strain HTLV III<sub>B</sub>. Fetal bovine serum, at a concentration of 5%, was present in the tissue culture fluids. Films of the virus were prepared by spreading 0.2 mL of undiluted virus suspension on the bottoms of sterile glass Petri dishes. Films were kept at 25°C and ambient humidity for 35 minutes, and further dried for 30 minutes at 37°C. Dried virus films were exposed to 2.0 mLs of the use solution for 10 minutes at 25°C. Following exposure, the plate was scraped to resuspend the contents and the virus-disinfectant mixture was immediately added to 18 mL of LBS broth. The mixture ( $10^{-2}$  dilution) was immediately titrated by serial dilution and assayed for infectivity. The MT-2 cell line, which exhibits lytic Cytopathic Effect (CPE) in the presence of HIV, was used as the indicator cell line in the infectivity assays. Dilutions of virus-disinfectant mixtures and the controls were inoculated into the MT-2 cell cultures in quadruplicate. The cultures were inoculated with 200  $\mu$ L of each dilution and 50  $\mu$ L of MT-2 cells were added. The cultures were incubated at 36-38°C in 5-7% CO<sub>2</sub>. The cells were observed for 7 days and CPE and cytotoxicity were recorded. The test results were calculated by the method of Karber. Controls included virus and cytotoxicity controls.

Note: The use directions for disinfecting non-food contact surfaces call for a 2% solution for the control of viruses (see page 9 of the proposed label); whereas, the efficacy testing described above used only a 1% solution (a less concentrated solution).

## V RESULTS:

MRID Number	Organism	Results		Dried Virus Control
		Lot No. 1698	Lot No. 2050	
456371-01	HIV 1 virus	$\leq 10^{2.5}$	$\leq 10^{2.5}$	$10^{6.75}$

Results expressed in TCID<sub>50</sub>/0.2mL.

## VI CONCLUSIONS:

The submitted efficacy data (MRID 456371-01) appear to support the use of a 1% solution of the product, Virkon S, as a virucide when tested against HIV type 1 virus, in the presence of 400 ppm hard water and a 5% organic soil load (fetal bovine serum) on hard, non-porous surfaces for a contact time of 10 minutes. Cytotoxicity was observed at the  $10^{-2}$  dilution. Complete inactivation (no growth) was indicated in the  $10^{-3}$  through  $10^{-7}$  dilutions. A 4-log reduction beyond the cytotoxic level was evident.

## VII LABELING COMMENTS:

1. The proposed label claims (as supported by MRID 456371-01) are not currently acceptable regarding the use of the product as a disinfectant against "Human Immuno-Deficiency Virus (HIV)" for a contact time of 10 minutes (or until air-dried). The proposed label needs to clearly indicate that efficacy relates specifically to HIV type 1. In addition, the proposed label needs to clearly indicate that efficacy relates to hard, non-porous surfaces.
2. Text on page 9 of the proposed label states: "With Virkon S, only one product is needed to clean and disinfect all surfaces." This language should be deleted. The statement "Do Not Use Virkon® S on acid-sensitive surfaces such as marble or soft metals such as copper, brass, or aluminum" would make the above statement mute.
3. No specific microorganisms are listed; there is no asterisk (\*) to a list of organisms elsewhere. However, the proposed and last accepted labels do include lists of animal health pathogens and human health pathogens.
4. The levels of hard water and organic material are not indicated on label.
5. Although disinfection use directions were provided, the proposed label did not include special instructions for cleaning and decontaminating against HIV-1 on pre-cleaned surfaces or objects soiled with blood/body fluids.
6. On page 1, delete the statement "For Use in Emergency Disease Control (OPT)."
7. On page 8, delete the statement "EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)."
8. On page 9, delete the directions for cleaning and disinfecting food contact surfaces.
9. On page 9, under sanitizing toilet bowls the label must state that the bowl must be emptied before adding product. Dilution factor must take in account of water in toilet bowl.





456371-00

March 22, 2002

Mr. Adam Heyward, PM #34  
Antimicrobials Branch  
US EPA  
Washington, DC 20460

Subject: Virkon S; EPA Reg. No. 62432-1; Proposed Amendment to Label

Dear Adam:

Enclosed please find the following documents in support of an amendment to the Virkon S label:

- Application for Pesticide Registration (EPA Form 8570-1)
- Proposed Product Label (5 copies with proposed changes highlighted)
- Current Stamped Label
- Certification with Respect to Citation of Data and Data Matrix (EPA Form 8570-34 and 8570-35)
- Supporting Data (1 study)

The proposed label includes previously approved text drawn from the Virkon label (EPA Reg. No. 62432-2). If you recall, the formulations for Virkon S and Virkon are substantially similar thus I do not foresee any risk assessment issues associated with adding these uses to the Virkon S label. I have been careful to separate those proposed uses which are related to animal health disease pathogens or organisms and those related to human health pathogens. In addition to adding claims from the Virkon label, I am submitting efficacy data to support adding an HIV claim.

The proposed label includes new use patterns: greenhouses, horticulture, aquaculture and emergency response and cleanup. The current registrations for Virkon S and Virkon cover a wide variety of animal and human health use patterns involving treatment of inanimate environmental surfaces and equipment. The new uses are also aimed at treating similar surfaces and equipment and do not pose significantly different human health or environmental risks.

Finally I have updated the First Aid statements to comply with PR Notice 2001-1 and the new labeling regulations published at 66 FR 64759 (12/14/01).

Let me know if you have any questions regarding this submission or if I need to supply additional information. Thanks for your assistance.

Sincerely,

T. Jeffrey Jones, Agent  
Antec International Ltd.  
Enclosures



March 22, 2002

Mr. Adam Heyward, PM #34  
Antimicrobials Branch  
US EPA  
Washington, DC 20460

**re: Virkon S; EPA Reg. No. 62432-1; Data Submission**

Dear Adam:

Enclosed please find the following data submitted in support of amendment of the Virkon S label to add an HIV claim:

- Volume 1 of 1  
10 Minute Inactivation of Human Immunodeficiency Virus Type 1 by Virkon S  
MRID# **45637101**

If you have any questions regarding this submission, please contact me as soon as possible.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeff Jones", is written over a circular stamp. The signature is fluid and cursive.

T. Jeffrey Jones, Agent  
Antec International Ltd.





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number  
231218

## Application for Pesticide - Section I

1. Company/Product Number 62432-1	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Virkon S	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd. c/o Delta Analytical Corp. 7910 Woodmont Ave., Suite 1000 Bethesda, MD 20814  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 62432-2 Product Name Virkon	

## Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment to add uses previously approved on Virkon label (EPA Reg. No. 62432-2); to add Greenhouse and Horticulture Uses; to add Aquaculture Uses; to add Emergency Response and On-site Cleanup uses; to add HIV claim; and to update and relocate First Aid language.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Jeff Jones	Title Agent, Antec International Ltd.	Telephone No. (Include Area Code) 301 652 5495
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent, Antec International Ltd.	
4. Typed Name Jeff Jones	5. Date 21 MARCH 2002	





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

## Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number  
Antec International Ltd. c/o Delta Analytical Corporation; 301 652 5495

EPA Registration Number/File Symbol  
62432-1

Active Ingredient(s) and/or representative test compound(s)  
potassium peroxydisulfate; sodium chloride

Date  
22 March 2002

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)  
Indoor

Product Name  
Virkon S

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

## SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

## SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

## SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

22 MAR 02

Typed or Printed Name and Title

Jeff Jones, Agent, Antec International Ltd.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 22 March 2002			EPA Reg No./File Symbol 62432-1		Page 1 of 3
Applicant's/Registrant's Name & Address Antec International Ltd. c/o Delta Analytical Corp., 7910 Woodmont Ave., Ste. 1000, Bethesda, MD 20814			Product Virkon S		
Ingredient potassium peroxymonosulfate; sodium chloride					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-8302	Color	see Note 1	A. H. Robins	PER	2
830-6303	Physical state	-Do-	-Do-	-Do-	-Do-
830-6304	Odor	-Do-	-Do-	-Do-	-Do-
830-6314	Oxidation/Reduction	-Do-	-Do-	-Do-	-Do-
830-6315	Flammability/flame extension	N/A			3
830-6316	Explosibility	N/A			4
830-7100	Viscosity	N/A			5
830-1650	Description of formulation process	-Do-	A. H. Robins	-Do-	-Do-
830-1670	Discussion of formation of impurities	-Do-	-Do-	-Do-	-Do-
830-1800	Enforcement analytical method	-Do-	-Do-	-Do-	-Do-
830-6317	Storage stability	-Do-	-Do-	-Do-	-Do-
830-6320	Corrosion characteristics	-Do-	-Do-	-Do-	-Do-
Signature <i>Jeff Jones</i>			Name and Title Jeff Jones, Agent, Antec International Ltd.		Date 22 MAR 02





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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## DATA MATRIX

Date 22 March 2002

EPA Reg No./File Symbol 62432-1

Page 2 of 3

Applicant's/Registrant's Name &amp; Address

Antec International Ltd, c/o Delta Analytical Corp., 7910 Woodmont Ave., Ste. 1000, Bethesda, MD 20814

Product

Virkon S

Ingredient potassium peroxydisulfate; sodium chloride

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
81-1	Acute oral toxicity	41057402	A. H. Robins	PER	2
81-2	Acute dermal toxicity	41057403	-Do-	-Do-	-DO-
81-3	Acute inhalation toxicity	41057404	-Do-	-Do-	-DO-
81-4	Primary skin irritation	41057405	-Do-	-Do-	-DO-
81-4	Primary skin irritation	41057406	-Do-	-Do-	-DO-
81-5	Primary eye irritation	41057407	-Do-	-Do-	-DO-
81-5	Primary eye irritation	41057408	-Do-	-Do-	-DO-
81-6	Skin sensitization	41057409	-Do-	-Do-	-DO-

Signature

Name and Title

Jeff Jones, Agent, Antec International Ltd.

Date

22 MAR 02





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 22 March 2002

EPA Reg No./File Symbol 62432-1

Page 3 of 3

Applicant's/Registrant's Name & Address

Antec International Ltd. c/o Delta Analytical Corporation 7910 Woodmont Ave. Suite 1000 Bethesda, MD 20814

Product

Virkon S

Ingredient potassium peroxydisulfate & sodium chloride

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
91-2	Product Performance	41057410	A.H. Robins	PER	2
-DO-	-DO-	41057411	-DO-	-DO-	-DO-
-DO-	-DO-	41108301	-DO-	-DO-	-DO-
-DO-	-DO-	41108302	-DO-	-DO-	-DO-
-DO-	-DO-	41259701	-DO-	-DO-	-DO-
-DO-	-DO-	41259702	-DO-	-DO-	-DO-
-DO-	-DO-	to be assigned	Antec International Ltd.	own	6

Signature

Jeff Jones

Name and Title

Jeff Jones, Agent, Antec International Ltd.

Date

22 MAR 02

EPA

3 25 02

## DATA MATRIX NOTES

Virkon S (EPA Reg. No. 62432-1)

22 March 2002

1. Neither A.H. Robins or Antec International are able to locate copies of the data previously submitted. Consequently both studies identified as addressing Product Chemistry requirements for the formulation in an NPIRS search are referenced for each data requirement. The MRID numbers for these studies are 42092401 and 41057401.
2. A letter from Timothy T. Slater of A.H. Robins Corporation granting Antec permission to cite this data is attached.
3. Virkon S is manufactured in powdered form. It is neither a combustible liquid or aerosol; flammability is not applicable.
4. Virkon S contains no explosive ingredients. Explodability is not applicable.
5. Virkon S is manufactured in powdered form. Viscosity is not applicable.
6. Study titled "10 Minute Inactivation of Human Immunodeficiency Virus Type 1 by Virkon S" submitted with current amendment package.





# AMERICAN HOME PRODUCTS CORPORATION

FIVE GIRALDA FARMS, MADISON, NEW JERSEY 07940 (973) 660-6535, FAX (973) 660-7176

January 17, 2001

**TIMOTHY T. SLATER**  
ASSOCIATE GENERAL COUNSEL

Ms. Linda S. Propst, Chief  
Product Registration Branch, SRRD  
Office of Pesticide Programs  
US Environmental Protection Agency  
Washington, DC, 20460

Dear Ms. Propst:

A. H. Robins Company ("Robins") is a subsidiary of American Home Products Corporation and I am counsel to and Assistant Secretary of Robins. In those capacities I am writing on behalf of Robins to grant Antec International Ltd., Chilton Industrial Estate, Sudbury, Suffolk CO10 6XD, England permission to cite data listed in Attachment I presently owned by Robins. I understand this data will be cited in support of reregistration of Virkon S (EPA Reg. No. 62432-1) and Virkon (EPA Reg. No. 62432-2).

As the original registrant of Virkon S (EPA Reg. No. 778-91), Robins submitted extensive data in support of its registration. The registration itself was officially transferred to Antec International in 1992. At that time, the intent was to transfer data rights as well, but I understand that has not been formally accomplished. Robins will be submitting the appropriate documents to accomplish that objective shortly.

In the interim, Robins grants Antec permission to cite all Virkon S data presently owned by Robins.

If you have any questions regarding this matter, please contact me.

Very truly yours,

Timothy T. Slater

cc: Jeff Jones, Delta Analytical Corporation

SUBMISSION BAR CODE # 5617597

REVIEWER R. Whitaker

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 62432-1 PM 34 ACTION CODE 302

DESCRIPTOR Label revision

☐ CHILD RESISTANT PACKAGING: ☐ CERTIFICATION  
☐ NON-RESIDENTIAL USE ONLY  
☐ NOT APPLICABLE

REGISTRATION TYPE: ☐ CONDITIONAL ☐ UNCONDITIONAL

PROPOSED CLASSIFICATION: ☐ GENERAL ☐ RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

6 17 02

6 19 02

6 25 02

~~METHOD OF SUPPORT~~

~~FORMULATORS EXEMPTION~~

☐ CITE ALL  
☐ SELECTIVE  
☐ NOT SUBMITTED  
☐ NOT APPLICABLE  
☐ INCORRECT/RESUB

☐ SUBMITTED  
☐ NOT SUBMITTED  
☐ NOT APPLICABLE  
☐ INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA  
PACK #

DATE  
SENT

DUE  
DATE

DATE  
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER


STATUS

RESPONSE CODE

17

RESPONSE DATE

AUG - 1 2002

238

AUG - 1 2002





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

AUG - 1 2002

Mr. T. Jeffrey Jones  
Delta Analytical Corporation  
Agent for Antec International Ltd.  
7910 Woodmont Avenue, Suite 1000  
Bethesda, MD 20814

Subject: **Virkon S**  
EPA Registration No. 62432-1  
Application Dated June 17, 2002

Dear Mr. Jones:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the following comments:

**Proposed Amendment**

- Revised Labeling to incorporate changes made by notification

**General Comments**

1. Revise the statement, "For Use in Emergency Disease Control (OPT)" to read similar to the following:

"For use in the control of animal health pathogens listed on the label and emergency disease out break"

2. Please explain meaning of the abbreviation "OPT". I assume it means "optional".

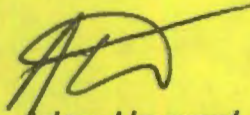
A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

If you have any questions concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,



Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

Enclosure



# Virkon® S

## BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities (OPT.)

Effective against Viruses  
(including CANINE PARVOVIRUS) • Bacteria • Fungi

For Use in Emergency Disease Control (OPT.)

For use in Cleaning and Disinfecting Institutional, Food Processing, and Service Facilities including food handling and food preparation areas of restaurants and food processing plants, stores, factories, schools, hotels, offices, ships, planes, transportation terminals, supermarkets and food warehouses. (OPT.)

For Use in Emergency Response and On-site Cleanup (emergency response calls, crime scenes, traffic accidents, fires, flood, natural and other disasters) e.g. cars, trucks, ambulances, and similar emergency apparatus, tires, wheels, floors, walls, ceilings, paved surfaces; and equipment such as SCBA, coats, boots, hats, masks, gloves, axes, Jaws of Life and similar emergency equipment. (OPT.)

For Use in Greenhouses, Horticulture, and Aquaculture (OPT.)

### ACTIVE INGREDIENTS:

Potassium peroxymonosulfate.....	20.4%
Sodium Chloride.....	1.5%
OTHER INGREDIENTS.....	78.1%
TOTAL.....	100.00%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

See [Back] [Side] Panel[s] [Inside Booklet] for Additional Precautions

**ACCEPTED**  
**with COMMENTS**  
**EPA Letter Dated:**

AUG - 1 2002

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 62432-1

## Front Panel Continued

**FIRST AID**

**Have the product container or label with you when calling a poison control center or doctor, or going for treatment.**

**If Swallowed:**

- Call Poison Control Center or doctor immediately for treatment advice.
- Have Person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor
- Do not give anything by mouth to an unconscious person

**If Inhaled:**

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a Poison Control Center or doctor for further treatment advice.

**If in Eyes:**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present after 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for further treatment advice.

**If on Skin:**

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center or doctor for further treatment advice.

**Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage.

\_\_\_ lbs. (\_\_\_) Net Weight

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

**Antec**  
**International**  
LEADERS IN BIOSECURITY

**Manufactured By:**

**ANTEC INTERNATIONAL LTD.**  
Windham Road, Chilton Industrial Estates  
Sudbury Suffolk CO10 6XD, England

Virkon® S is a registered trademark of and manufactured by Antec International Limited  
US Patent No. 4822512



[Comment: The list of claims (sites) under "EFFECTIVE AGAINST" may be placed in any order as long as each subheading and its contents remains intact.]

# **EFFECTIVE AGAINST FOLLOWING ANIMAL HEALTH PATHOGENS:**

## **EQUINE BACTERIA**

Clostridium perfringens  
Fistulous withers (Poll Evil)  
Taylorella equigenitalis  
Streptococcus equi (Strangles)  
Pseudomonas mallei  
(Glanders)  
Bordetella bronchiseptica

## **EQUINE VIRUSES**

African Horse Sickness  
Equine Viral Arteritis  
[Pink Eye]  
Coital Exanthema  
Myeloencephalopathy  
Rhinopneumonitis  
Equine Infectious Anemia  
(Swamp Fever)  
Equine papillomatosis  
Equine Contagious Abortion  
Adenovirus Pneumonia  
Equine Influenza (The Cough)

## **EQUINE FUNGI**

Trichophyton spp.  
(Ringworm)  
Trichophyton spp.  
(Mud Fever)  
Fusarium moniliforme

## **BOVINE BACTERIA**

Moraxella bovis  
Mycobacterium bovis  
Haemophilus somnus

## **BOVINE VIRUSES**

Calf rotavirus  
Infective Bovine  
Rhinotracheitis

## **Bovine Adenovirus Type 4**

Pseudorabies  
Foot & Mouth Disease

## **BOVINE FUNGI**

Fusarium moniliforme

## **POULTRY BACTERIA**

Streptococcus pyogenes  
Campylobacter pyloridis  
Klebsiella pneumoniae  
Escherichia coli  
Salmonella typhimurium  
Salmonella choleraesuis  
Pseudomonas aeruginosa  
Staphylococcus aureus  
Staphylococcus epidermidis  
Mycoplasma gallisepticum  
Clostridium perfringens  
Bordetella avium

## **POULTRY VIRUSES**

Newcastle Disease  
Infectious Bronchitis  
Infectious Bursal Disease  
Avian Laryngotracheitis  
Avian Influenza  
Marek's Disease  
Egg Drop Syndrome  
Adenovirus  
Turkey Herpes Virus  
Duck Herpes Virus  
Duck Viral Enteritis

## **POULTRY FUNGI**

Aspergillus flavus  
Aspergillus fumigatus  
Candida albicans

## **SWINE BACTERIA**

Bordetella bronchiseptica  
Pasteurella multocida  
Actinobacillus  
pleuropneumonia  
Treponema hyodysenteriae  
Clostridium perfringens

## **SWINE VIRUSES**

Hog Cholera  
Swine Influenza  
Porcine parvovirus  
Rotaviral diarrhea  
Vesicular stomatitis  
Pseudorabies  
Porcine Reproductive and  
Respiratory Syndrome  
(PRRS)  
African Swine Fever  
Foot and Mouth Disease

## **SWINE FUNGI**

Fusarium moniliforme

## **COMPANION ANIMALS**

### **BACTERIA**

Staphylococcus aureus  
Streptococcus pyogenes  
Klebsiella pneumoniae  
Pseudomonas aeruginosa

### **VIRUSES**

Canine Parvovirus  
Distemper  
Leptospira canicola  
Feline parvovirus  
Feline herpes  
Feline calicivirus

### **FUNGI**

Microsporum canis



**EFFECTIVE AGAINST THE FOLLOWING HUMAN HEALTH PATHOGENS**

Human Immuno-Deficiency Virus (HIV), Streptococcus pyogenes, Campylobacter pyloridis, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, and Candida albicans.

**PRECAUTIONARY STATEMENTS****HAZARDS TO HUMANS AND DOMESTIC ANIMALS****DANGER**

Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive statement refers to powder only not in use solution.

[Comment: The instructions under "DIRECTIONS FOR USE" may be placed in any order as long as they remain a continuous section on the label.]

**BROAD SPECTRUM DISINFECTANT**

Virkon<sub>S</sub> is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material. Virkon<sub>S</sub> passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water. Apply a 0.5% (1:200) solution for routine sanitation.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

**GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES**

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.
  2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.
  3. Empty all troughs, racks, and other feeding and watering appliances.
  4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
  5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
  6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
  7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.
  8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.
- This powder formula is easily diluted for use in manual or machine operations.



**Virkon® S DILUTION CHART**

Fill container with desired amount of water and add Virkon® S powder to achieve recommended solution concentration.

Quantity of Water	0.5% Solution	1% Solution	2% Solution
1 Quart	0.15 ounces	0.3 ounces	0.7 ounces
1 Gallon	0.65 ounces	1.3 ounces	2.7 ounces
10 Gallons	6.7 ounces	13.4 ounces	26.7 ounces
50 Gallons	33.4 ounces	66.8 ounces	133.5 ounces

1.3 oz. measuring scoop is provided. ~~Measuring cup provided.~~

Add [1.3 oz. (1 scoop) of Virkon® S [the contents of one Virkon® S packet] to one gallon of warm water. Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

### POULTRY [PRODUCTION] [AND RATITE PRODUCTION]

[CONTROLS: Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts - Aspergillus flavus, Aspergillus fumigatus and Candida albicans. Bacteria - Streptococcus pyogenes, Campylobacter pyloridis, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Bordetella avium and Mycoplasma gallisepticum.]

HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus).

Virkon® S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus). After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: Use Virkon® S at 0.5-1% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors.



## SWINE PRODUCTION

[CONTROLS: Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine Fever and Foot and Mouth Disease. Bacteria of Pleuropneumonia, Treponema hyodysenteriae, and Clostridium perfringens. Fungi: Fusarium moniliforme.]

Follow General Instructions to remove swine and preclean area to be treated. Virkon® S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants (use a 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus), and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

## EQUINE PRODUCTION

### BROAD SPECTRUM EQUINE DISINFECTANT/DETERGANT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

[CONTROLS: Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis. Bacterial: Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders). Fungi: Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), and Fusarium moniliforme.]

APPLICATIONS: For cleaning and disinfecting all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

#### USES:

Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution. Rinse with clean water.

Blankets, Saddle Pads and Rugs: Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

Aerial Spraying to control airborne diseases: Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon® S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.



## BOVINE PRODUCTION

[CONTROLS: Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies and Foot and Mouth Disease; Bacteria of *Maraxella bovis*, *Haemophilus somnus* and *Mycobacterium bovis*; Fungi of *Fusarium moniliforme*.]

Follow General Instructions to remove livestock and preclean area to be treated. A 1% solution of Virkon<sup>®</sup> S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

## COMPANION ANIMALS

[CONTROLS: Viruses Canine Parvovirus, Distemper, *Leptospira canicola*, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of *Staphylococcus aureus*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*; Fungi of *Microsporum canis*.]

[APPLICATIONS] A 1% solution of Virkon<sup>®</sup> S is recommended as a "one step" cleaning and disinfecting procedure for all surfaces, equipment, instruments, utensils and cages [caging systems] within [associated with] Veterinary Medical Hospitals, infectious disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon<sup>®</sup> S for long periods - 10 minutes is maximum contact time.

## GREENHOUSES AND HORTICULTURE

Virkon<sup>®</sup> S is intended to disinfect inanimate environmental surfaces, glasshouse structures, equipment, utensils, trays, containers, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

Remove all crop debris, strings and other deposits from structures, empty trays and pots. Power wash all the dust off the covering and superstructure and let dry. Using a sprayer or fogger saturate all surfaces with a 1% solution of Virkon<sup>®</sup> S. Let air dry.

Virkon<sup>®</sup> S may also be used to disinfect irrigation tanks and lines. Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon<sup>®</sup> S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog



(wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

### AQUACULTURE

Virkon<sup>®</sup> S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon<sup>®</sup> S may also be used in foot dips. Virkon<sup>®</sup> S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon<sup>®</sup> S solution followed by a water rinse.

Virkon<sup>®</sup> S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

### EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

**CONTROLS:** OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus.

A 1% solution of Virkon<sup>®</sup> S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment, airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray Virkon<sup>®</sup> S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon<sup>®</sup> S for long periods - 10 minutes is maximum contact time.



## INSTITUTIONAL, FOOD PROCESSING, AND SERVICE FACILITIES (HUMAN HEALTH)

**CONTROLS:** Human Immuno-Deficiency Virus (HIV), Streptococcus pyogenes, Campylobacter pyloridis, klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, and Candida albicans.

With Virkon<sup>®</sup> S, only one product is needed to clean and disinfect all surfaces.

**Do Not Use Virkon<sup>®</sup> S** on acid-sensitive surfaces such as marble or soft metals such as copper, brass, or aluminum. Avoid splashing Virkon<sup>®</sup> S solution on textiles or carpets. Virkon<sup>®</sup> S may be used on carpeting or other textiles only if area is tested for color fastness before use and treated area vacuumed when dry.

**Cleaning and Disinfecting Food Contact Surfaces:** Remove gross dirt and prepare 1.0% solution according to the Dilution Chart. Apply to surface using a sponge, brush, or spray device until the surface is visibly clean. Let stand for 10 minutes and rinse with potable water.

**Cleaning and Disinfecting Non-Food Contact Surfaces:** Remove gross dirt and use 1.0% Virkon<sup>®</sup> S solution prepared according to the Dilution Chart below. Apply to surface using a mop, sponge, brushes or spray device until the surface is visibly clean. Air dry. In cases of fungal or viral contamination of non-food contact surfaces, follow these instructions substituting a 2.0% Virkon<sup>®</sup> S solution.

**Sanitizing Toilet Bowls.** After flushing, sprinkle 1 oz. Virkon<sup>®</sup> S powder around the bowl, scrub with a brush, and leave for 10 minutes. Flush.

**Cleaning and Disinfecting Manikins Used in CPR Training:** Manikins should be cleaned as soon as possible at the end of each class to avoid drying of contaminants on surfaces. Disassemble the manikin as directed by the manufacturer's instructions. Thoroughly wash all internal and external surfaces and reusable protective face shields with a brush using a 1% Virkon<sup>®</sup> S solution. Let stand for 10 minutes and rinse with potable water.

### EMERGENCY RESPONSE AND ON-SITE CLEANUP

**Cover heavy spillage of body fluids with Virkon<sup>®</sup> S powder.** Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste.

**Prepare 2% Virkon<sup>®</sup> S solution according to the Dilution Chart.** Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

### STORAGE AND DISPOSAL

**STORAGE:** Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

**DISPOSAL:** Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals.



June 17, 2002

Mr. Adam Heyward, PM #34  
Antimicrobials Branch  
US EPA  
Washington, DC 20460

Subject: Virkon S; EPA Reg. No. 62432-1; Revised Amendment

Dear Adam:

Following up on our telephone conversation today, I am submitting a revised label in conjunction with an amendment proposal I originally submitted on March 21, 2002. After that amendment was submitted, I submitted a notification to correct typographical and printing errors on April 19, 2002. As I mentioned at the time, I viewed this notification as unnecessary, but at least one state took a contrary position. You accepted this notification by letter date May 8, 2002. The revised label I am submitting today incorporates the changes made by notification into our earlier substantive amendment proposal.

This submission includes:

- Application for Pesticide Registration (EPA Form 8570-1)
- Revised Product Label (5 copies with proposed changes highlighted)

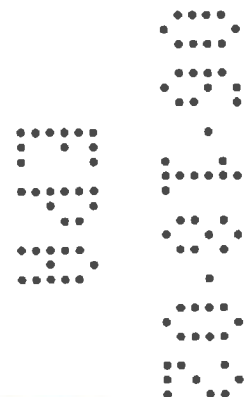
The substantive changes in the label are highlighted and I'm also attaching a one-page summary of the changes that were earlier accepted by notification.

Let me know if you have any questions regarding this submission or if I need to supply additional information. Thanks for your assistance.

Sincerely,



T. Jeffrey Jones, Agent  
Antec International Ltd.  
Enclosures





## SUMMARY OF TYPOGRAPHICAL CHANGES TO THE VIRKON-S LABEL

### APRIL 17, 2002

1. Add the following text in Signal Word section: [Inside Booklet]
2. The phrase "Effective against Viruses (Including CANINE PARVOVIRUS) • Bacteria • Fungi" adapted from page 2 of the label has been added to the front panel
3. Addition of the following manufacturer information.

ANTEC  
INTERNATIONAL  
LEADERS IN BIOSECURITY

Manufactured By:

4. Comment to appear on EPA stamped label clarifying order of Claims placement.  
[Comment: The list of claims (sites) under "EFFECTIVE AGAINST" may be placed in any order as long as each subheading and its contents remains intact.]
5. Addition of brackets under Equine Viruses: [Pink Eye]
6. Comment to appear on EPA stamped label clarifying order of Directions for Use placement.  
[Comment: The instructions under "DIRECTIONS FOR USE" may be placed in any order as long as they remain a continuous section on the label.]
7. Deletion of column header words: "Amount of Powder for"
8. Deletion of column header words: "Amount of Powder for"
9. Addition of brackets and word: [PRODUCTION]
10. Addition of brackets under "POULTRY" section.
11. Addition of brackets under "SWINE" section.
12. Addition of brackets under "EQUINE" section
13. Deletion of brackets under "POULTRY, SWINE, & EQUINE" sections.
14. Correct spelling of waterproof under the "SWINE" section.



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number  
231237

### Application for Pesticide - Section I

1. Company/Product Number 62432-1	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Virkon S	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd. c/o Delta Analytical Corp. 7910 Woodmont Ave., Suite 1000 Bethesda, MD 20814		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 62432-2 Product Name Virkon
<input type="checkbox"/> Check if this is a new address		

### Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Substitution of proposed label incorporating changes made by notification. Original amendment submitted March 22, 2002.

### Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Notification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Jeff Jones	Title Agent, Antec International Ltd.	Telephone No. (Include Area Code) 301 652 5495
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		Date Application Received (Stamped) 
2. Signature 	3. Title Agent, Antec International Ltd.	
4. Typed Name Jeff Jones	5. Date 17 June 2002	



SUBMISSION BAR CODE # 9614981REVIEWER R. WhitakerCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 62432-1 PM 34 ACTION CODE 332DESCRIPTOR Correction of typographical errors

☐ CHILD RESISTANT PACKAGING: ☐ CERTIFICATION  
☐ NON-RESIDENTIAL USE ONLY  
☐ NOT APPLICABLE

REGISTRATION TYPE: ☐ CONDITIONAL ☐ UNCONDITIONALPROPOSED CLASSIFICATION: ☐ GENERAL ☐ RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

4 10 024 26 024 30 02~~METHOD OF SUPPORT~~~~FORMULATORS EXEMPTION~~

☐ CITE ALL  
☐ SELECTIVE  
☐ NOT SUBMITTED  
☐ NOT APPLICABLE  
☐ INCORRECT/RESUB

☐ SUBMITTED  
☐ NOT SUBMITTED  
☐ NOT APPLICABLE  
☐ INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA  
PACK #DATE  
SENTDUE  
DATEDATE  
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

RESPONSE CODE

17

RESPONSE DATE

MAY -8 2002





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

MAY - 8 2002

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Mr. Jeff Jones, Agent for  
Antec International Ltd.  
c/o Delta Analytical Corp.  
7910 Woodmont Avenue, Suite 1000  
Bethesda, MD 20814

Subject: Notification in Accordance with PR Notice 98-10  
**Virkon S**  
EPA Registration Number 62432-1  
Application dated April 19, 2002

Dear Mr. Jones:

This will acknowledge receipt of your notification, submitted under the provisions of PR Notice 98-10, FIFRA section 3 (c) 9.

**Proposed Notification:**

- Correction of typographical and printing errors.

**General Comment:**

Based on a review of the material submitted, the following comment apply.

A copy of the notification has been inserted in your file for future reference.

Should you have any questions concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,

A handwritten signature in black ink, appearing to read "AH", written over a horizontal line.

Adam Heyward  
Product Manager 34  
Regulatory Management Branch II  
Antimicrobials Division (7510C)



**VIRKON-S<sup>®</sup>**  
**BROAD SPECTRUM DISINFECTANT**

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities

Effective against Viruses  
(including CANINE PARVOVIRUS) • Bacteria • Fungi

**NOTIFICATION**  
Date Reviewed: 4.30.02  
Reviewed By: R Whitehead

**ACTIVE INGREDIENTS:**

Potassium peroxymonosulfate.....	20.4%
Sodium Chloride.....	1.5%
INERT INGREDIENTS.....	78.1%
TOTAL.....	100.00%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

See [Back] [Side] Panel[s] [Inside Booklet] for Additional Precautions

\_\_\_ lbs. (\_\_\_) Net Weight

EPA Reg. No. 62432-1

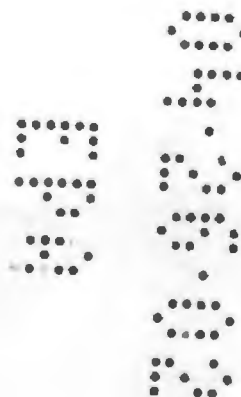
EPA Est. No. 62432-EN-001

**Antec**  
**International**  
LEADERS IN BIOSECURITY

Manufactured By:

**NOTIFICATION**  
Date Reviewed: 4.30.02  
Reviewed By: R Whitehead

**ANTEC INTERNATIONAL LTD.**  
Windham Road, Chilton Industrial Estate  
Sudbury, Suffolk, UK  
C010 2XD



VIRKON S is a registered trademark of and manufactured by Antec International Limited  
US Patent No. 4822512

[Comment: The list of claims (sites) under "EFFECTIVE AGAINST" may be placed in any order as long as each subheading and its contents remains intact.]

#### EQUINE BACTERIA

*Clostridium perfringens*  
Fistulous withers (Poll Evil)  
*Taylorella equigenitalis*  
*Streptococcus equi* (Strangles)  
*Pseudomonas mallei*  
(Glanders)  
*Bordetella bronchiseptica*

#### EQUINE VIRUSES

African Horse Sickness  
Equine Viral Arteritis  
[Pink Eye]  
Coital Exanthema  
Myeloencephalopathy  
Rhinopneumonitis  
Equine Infectious Anemia  
(Swamp Fever)  
Equine papillomatosis  
Equine Contagious Abortion  
Adenovirus Pneumonia  
Equine Influenza (The Cough)

#### EQUINE FUNGI

*Trichophyton* spp.  
(Ringworm)  
*Trichophyton* spp.  
(Mud Fever)  
*Fusarium moniliforme*

#### BOVINE BACTERIA

*Moraxella bovis*  
*Mycobacterium bovis*  
*Haemophilus somnus*

#### BOVINE VIRUSES

Calf rotavirus  
Infective Bovine  
Rhinotracheitis  
Bovine Adenovirus Type 4  
Pseudorabies  
Foot & Mouth Disease

#### EFFECTIVE AGAINST:

##### BOVINE FUNGI

*Fusarium moniliforme*

##### POULTRY BACTERIA

*Streptococcus pyogenes*  
*Campylobacter pyloridis*  
*Klebsiella pneumoniae*  
*Escherichia coli*  
*Salmonella typhimurium*  
*Salmonella choleraesuis*  
*Pseudomonas aeruginosa*  
*Staphylococcus aureus*  
*Staphylococcus epidermidis*  
*Mycoplasma gallisepticum*  
*Clostridium perfringens*  
*Bordetella avium*

##### POULTRY VIRUSES

Newcastle Disease  
Infectious Bronchitis  
Infectious Bursal Disease  
Avian Laryngotracheitis  
Avian Influenza  
Marek's Disease  
Egg Drop Syndrome  
Adenovirus  
Turkey Herpes Virus  
Duck Herpes Virus  
Duck Viral Enteritis

##### POULTRY FUNGI

*Aspergillus flavus*  
*Aspergillus fumigatus*  
*Candida albicans*

##### SWINE BACTERIA

*Bordetella bronchiseptica*  
*Pasteurella multocida*  
*Actinobacillus*  
pleuropneumonia  
*Treponema hyodysenteriae*  
*Clostridium perfringens*

##### SWINE VIRUSES

Hog Cholera  
Swine Influenza  
Porcine parvovirus  
Rotaviral diarrhea  
Vesicular stomatitis  
Pseudorabies  
Porcine Reproductive and  
Respiratory Syndrome  
(PRRS)  
African Swine Fever  
Foot and Mouth Disease

##### SWINE FUNGI

*Fusarium moniliforme*

#### COMPANION ANIMALS BACTERIA

*Staphylococcus aureus*  
*Streptococcus pyogenes*  
*Klebsiella pneumoniae*  
*Pseudomonas aeruginosa*

#### VIRUSES

Canine Parvovirus  
Distemper  
*Leptospira canicola*  
Feline parvovirus  
Feline herpes  
Feline calicivirus

#### FUNGI

*Microsporum canis*



**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
DANGER**

Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive statement refers to powder only not in use solution.

**FIRST AID**

**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention if irritation persists.

**IF INHALED:** If symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

**IF SWALLOWED:** Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

**NOTICE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

[Comment: The instructions under "DIRECTIONS FOR USE" may be placed in any order as long as they remain a continuous section on the label.]

**BROAD SPECTRUM DISINFECTANT**

VIRKON-S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material. VIRKON-S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

**General Instructions—Poultry and Farm Premises**

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.
2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.



5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.
8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

This powder formula is easily diluted for use in manual or machine operations.

#### **VIRKON-S DILUTION CHART**

*Fill container with desired amount of water and add VIRKON-S powder to achieve recommended solution concentration.*

<i>Quantity of Water</i>	<i>Amount of Powder for 1% Solution</i>	<i>Amount of Powder for 2% Solution</i>
<i>1 Quart</i>	<i>0.3 ounces</i>	<i>0.7 ounces</i>
<i>1 Gallon</i>	<i>1.3 ounces</i>	<i>2.7 ounces</i>
<i>10 Gallons</i>	<i>13.4 ounces</i>	<i>26.7 ounces</i>
<i>50 Gallons</i>	<i>66.8 ounces</i>	<i>133.5 ounces</i>

*1.3 oz. measuring scoop is provided.*

Add [1.3 oz. (1 scoop) of VIRKON-S] [the contents of one VIRKON-S packet] to one gallon of warm water. Solutions are stable for 7 days. Do not soak metal objects in VIRKON-S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

#### **POULTRY [PRODUCTION] [AND RATITE PRODUCTION]**

**CONTROLS:** Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*. Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium* and *Mycoplasma gallisepticum*.)

**HATCHERIES:** VIRKON-S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). VIRKON-S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting



procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

**BROILER/BREEDER HOUSES:** Follow General Instructions above to remove poultry and preclean area to be treated. Spray floors and walls with VIRKON-S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of VIRKON-S (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus). After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

**FOR AIR SANITIZING:** Use VIRKON-S at 1-2% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

**PROCESSING PLANTS:** Spray VIRKON-S at 1% solution to disinfect and clean walls, ceilings and floors.

### SWINE [PRODUCTION]

**CONTROLS:** Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine Fever and Foot and Mouth Disease. Bacteria of Pleuropneumonia, Treponema hyodysenteriae, and Clostridium perfringens. Fungi: Fusarium moniliforme.

Follow General Instructions above to remove swine and preclean area to be treated. VIRKON-S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants (use a 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus), and agricultural production equipment such as trucks, ~~waterproof~~ footwear (such as rubber boots), and associated livestock equipment and instruments.

VIRKON-S at 1-2% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

### EQUINE [PRODUCTION]

**BROAD SPECTRUM EQUINE DISINFECTANT/DETERGANT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION**

#### **CONTROLS**

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis. Bacterial: Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella



equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders). Fungi: Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), and Fusarium moniliforme.]

**APPLICATIONS:** For cleaning and disinfecting all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc].

**USES:**

Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% VIRKON-S solution. Rinse with clean water.

Blankets, Saddle Pads, and Rugs: Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

Aerial Spraying to control airborne diseases: Use a hand [for knapsack] sprayer with fine setting, or an automatic spraying system. Spray a 1% VIRKON-S solution for 2-3 minutes twice daily [first thing in the morning and last thing at night]. Rinse sprayers with water after use.

**BOVINE [PRODUCTION]**

**CONTROLS:** Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies and Foot and Mouth Disease; Bacteria of Maraxella bovis, Haemophilus somnus and Mycobacterium bovis; Fungi of Fusarium moniliforme.]

Follow General Instructions above to remove livestock and preclean area to be treated. A 1% solution of VIRKON-S is recommended to clean and disinfect areas associated with bovine housing, stabling, hospital [quarantine] pens, feedlot facilities, and agricultural production equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

**COMPANION ANIMALS**

**CONTROLS:** Viruses Canine Parvovirus, Distemper, Leptospira canicola, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa; Fungi of Microsporum canis.]

**[APPLICATIONS:]** A 1% solution of VIRKON-S is recommended as a "one step" cleaning and disinfecting procedure for all surfaces, equipment, instruments, utensils and cages, [caging systems] within [associated with] [Veterinary Medical Hospitals,] [infections disease wards,] [quarantine areas,] [Humane Society facilities,] [laboratory animal quarters,] grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in VIRKON-S for long periods - 10 minutes is maximum contact time.



## EMERGENCY DISEASE CONTROL

### CONTROLS: Foot and Mouse Disease Virus

A 1% solution of VIRKON-S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray VIRKON-S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in VIRKON-S for long periods - 10 minutes is maximum contact time.

### STORAGE AND DISPOSAL

**STORAGE:** Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

**DISPOSAL:** Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals

34



April 19, 2002

Mr. Adam Heyward, PM #34  
Antimicrobials Branch  
US EPA  
Washington, DC 20460

Subject: Virkon S; EPA Reg. No. 62432-1; Notification of Correction of Typographical Errors

Dear Adam:

Enclosed please find the following documents pursuant to a notification of the correction of typographical errors on the Virkon S label.

- Application for Pesticide Registration (EPA Form 8570-1)
- Proposed Product Label (5 copies with proposed changes highlighted)
- Current Stamped Label

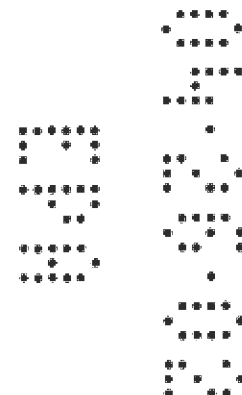
To expedite your review I have attached a short summary of the proposed changes.

Let me know if you have any questions regarding this submission or if I need to supply additional information. Thanks for your assistance.

Sincerely,

A handwritten signature in blue ink, appearing to read 'T. Jeffrey Jones', is written over a light blue circular stamp.

T. Jeffrey Jones, Agent  
Antec International Ltd.  
Enclosures





## SUMMARY OF TYPOGRAPHICAL CHANGES TO THE VIRKON-S LABEL

### APRIL 17, 2002

1. Add the following text in Signal Word section: [Inside Booklet]
2. The phrase "Effective against Viruses (Including CANINE PARVOVIRUS) ● Bacteria ● Fungi" adapted from page 2 of the label has been added to the front panel
3. Addition of the following manufacturer information.

ANTEC  
INTERNATIONAL  
LEADERS IN BIOSECURITY

Manufactured By:

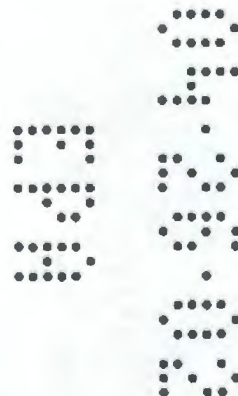
4. **Comment to appear on EPA stamped label clarifying order of Claims placement.**

[Comment: The list of claims (sites) under "EFFECTIVE AGAINST" may be placed in any order as long as each subheading and its contents remains intact.]

5. Addition of brackets under Equine Viruses: [Pink Eye]
6. Comment to appear on EPA stamped label clarifying order of Directions for Use placement.

**[Comment: The instructions under "DIRECTIONS FOR USE" may be placed in any order as long as they remain a continuous section on the label.]**

7. Deletion of column header words: "Amount of Powder for"
8. Deletion of column header words: "Amount of Powder for"
9. Addition of brackets and word: [PRODUCTION]
10. Addition of brackets under "POULTRY" section.
11. Addition of brackets under "SWINE" section.
12. Addition of brackets under "EQUINE" section
13. Deletion of brackets under "POULTRY, SWINE, & EQUINE" sections.
14. Correct spelling of waterproof under the "SWINE" section.







United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

258552

## Application for Pesticide - Section I

1. Company/Product Number 62432-1	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Virkon S	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd. c/o Delta Analytical Corp. 7910 Woodmont Ave., Suite 1000 Bethesda, MD 20814  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____  Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of correction of typographical and printing errors.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 USC Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Notification must be submitted					
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Jeff Jones	Title Agent, Antec International Ltd.	Telephone No. (Include Area Code) 301 652 5495
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)    
2. Signature 	3. Title Agent, Antec International Ltd.	
4. Typed Name Jeff Jones	5. Date 19 April 02	

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United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

258552

## Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code)  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name	Title	Telephone No. (Include Area Code)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			Date Application Received (Stamped) 
2. Signature	3. Title		
4. Typed Name	5. Date		



## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

**Submission of Labeling** - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data** - Data submitted in support of this application must be submitted in accordance with PR Notice 88-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A** - Check the appropriate action for which you are submitting this form.

**SECTION I** - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II** - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III** (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which Label is affixed to product** - Indicate the method product label is attached to retail container.

**SECTION IV** (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "no-reg," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



SUBMISSION BAR CODE 5611744 REVISOR A. Peters

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 62432-1 PM 34 ACTION CODE 332

DESCRIPTOR Correction of typographical errors on label

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION  
[ ] NON-RESIDENTIAL USE ONLY  
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION EPA RECEIVE DATE PM RECEIVE DATE

2 12 02

3 4 02

3 6 02

METHOD OF SUPPORT

FORMULATORS EXEMPTION

[ ] CITE-ALL  
[ ] SELECTIVE  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

[ ] SUBMITTED  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED DATA DATE DUE DATE  
PACK # SENT DATE RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

RESPONSE CODE

17

RESPONSE DATE

MAR 18 2002



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 18 2002

Jeff Jones  
Agent  
Antec International Ltd.  
7910 Woodmont Ave Suite 1000  
Bethesda, MD 20814

Subject: Notification Per PR Notice 98 -10  
Virkon S  
EPA Registration No. 62432-1  
Application Dated: February 1, 2002

Dear Mr. Jeff Jones,

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3 (c) 9.

**Proposed Notification**

Corrections of typographical and printing errors on the Virkon S label

- Change the value for the Inert ingredient from 77.1 % to 78.1 %
- Add the phrase "in Virkon-S" in general instructions
- Change the spelling of "Treponema hyodysenteria" to "Treponema hyodysenteriae"
- Change "Viral Arteritis" to Equine Arteritis"
- Change "Streptococcus Aureus" to "Staphylococcus Aureus"

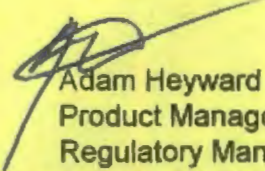
**General Comments**

Based on a review of the material submitted, the following comments apply:

This notification application is acceptable and a copy has been made a part of the records for this file.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422.

Sincerely,

  
Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobial Division (7510C)

CONCURRENCES

SYMBOL	7510(C)							
SURNAME	A. Peters							
DATE	3/15/02							

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**VIRKON-S®**  
**BROAD SPECTRUM DISINFECTANT**

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities

**ACTIVE INGREDIENTS:**

Potassium peroxymonosulfate..... 20.4%

Sodium Chloride..... 1.5%

INERT INGREDIENTS..... 78.1%

TOTAL..... 100.00%

**NOTIFICATION**

Date Reviewed: 3-18-02  
Reviewed By: A. Peter 3

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

See Back [Side] Panel[s] for Additional Precautions

\_\_\_ lbs. (\_\_\_) Net Weight

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

**ANTEC INTERNATIONAL LTD.**  
Windham Road, Chilton Industrial Estates  
Sudbury Suffolk CO10 6XD, England  
Tel: (1787) 77305 Telex: 987495 Fax: (1787) 310846

VIRKON S is a registered trademark of and manufactured by Antec International Limited  
US Patent No. 4822512



**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
DANGER**

Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive statement refers to powder only not in use solution.

**FIRST AID**

**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention if irritation persists.

**IF INHALED:** If symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

**IF SWALLOWED:** Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

**NOTICE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

**BROAD SPECTRUM DISINFECTANT**

VIRKON-S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material. VIRKON-S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

**General Instructions—Poultry and Farm Premises**

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.
2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.



# EFFECTIVE AGAINST:

## EQUINE BACTERIA

Clostridium perfringens  
Fistulous withers (Poll Evil)  
Taylorella equigenitalis  
Streptococcus equi (Strangles)  
Pseudomonas mallei  
(Glanders)  
Bordetella bronchiseptica

## EQUINE VIRUSES

African Horse Sickness  
Equine Viral Arteritis  
(Pink Eye)  
Coital Exanthema  
Myeloencephalopathy  
Rhinopneumonitis  
Equine Infectious Anemia  
(Swamp Fever)  
Equine papillomatosis  
Equine Contagious Abortion  
Adenovirus Pneumonia  
Equine Influenza (The Cough)

## EQUINE FUNGI

Trichophyton spp.  
(Ringworm)  
Trichophyton spp.  
(Mud Fever)  
Fusarium moniliforme

## BOVINE BACTERIA

Moraxella bovis  
Mycobacterium bovis  
Haemophilus somnus

## BOVINE VIRUSES

Calf rotavirus  
Infective Bovine  
Rhinothraheitis  
Bovine Adenovirus Type 4  
Pseudorabies  
Foot & Mouth Disease

## BOVINE FUNGI

Fusarium moniliforme

## POULTRY BACTERIA

Streptococcus pyogenes  
Campylobacter pyloridis  
Klebsiella pneumoniae  
Escherichia coli  
Salmonella typhimurium  
Salmonella choleraesuis  
Pseudomonas aeruginosa  
Staphylococcus aureus  
Staphylococcus epidermidis  
Mycoplasma gallisepticum  
Clostridium perfringens  
Bordetella avium

## POULTRY VIRUSES

Newcastle Disease  
Infectious Bronchitis  
Infectious Bursal Disease  
Avian Laryngotracheitis  
Avian Influenza  
Marek's Disease  
Egg Drop Syndrome  
Adenovirus  
Turkey Herpes Virus  
Duck Herpes Virus  
Duck Viral Enteritis

## POULTRY FUNGI

Aspergillus flavus  
Aspergillus fumigatus  
Candida albicans

## SWINE BACTERIA

Bordetella bronchiseptica  
Pasteurella multocida  
Actinobacillus  
pleuropneumonia  
Treponema hyodysenteriae  
Clostridium perfringens

## SWINE VIRUSES

Hog Cholera  
Swine Influenza  
Porcine parvovirus  
Rotaviral diarrhea  
Vesicular stomatitis  
Pseudorabies  
Porcine Reproductive and  
Respiratory Syndrome  
(PRRS)  
African Swine Fever  
Foot and Mouth Disease

## SWINE FUNGI

Fusarium moniliforme

## COMPANION ANIMALS

### BACTERIA

Streptococcus Staphylococcus  
aureus  
Streptococcus pyogenes  
Klebsiella pneumoniae  
Pseudomonas aeruginosa

### VIRUSES

Canine Parvovirus  
Distemper  
Leptospira canicola  
Feline parvovirus  
Feline herpes  
Feline calicivirus

### FUNGI

Microsporium canis



6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.
8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

This powder formula is easily diluted for use in manual or machine operations.

#### **VIRKON-S DILUTION CHART**

*Fill container with desired amount of water and add VIRKON-S powder to achieve recommended solution concentration.*

<i>Quantity of Water</i>	<i>Amount of Powder for 1% Solution</i>	<i>Amount of Powder for 2% Solution</i>
<i>1 Quart</i>	<i>0.3 ounces</i>	<i>0.7 ounces</i>
<i>1 Gallon</i>	<i>1.3 ounces</i>	<i>2.7 ounces</i>
<i>10 Gallons</i>	<i>13.4 ounces</i>	<i>26.7 ounces</i>
<i>50 Gallons</i>	<i>66.8 ounces</i>	<i>133.5 ounces</i>

*1.3 oz. measuring scoop is provided.*

Add [1.3 oz. (1 scoop) of VIRKON-S] [the contents of one VIRKON-S packet] to one gallon of warm water. Solutions are stable for 7 days. Do not soak metal objects in VIRKON-S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

#### **POULTRY [AND RATITE PRODUCTION]**

**CONTROLS:** Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*. Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium* and *Mycoplasma gallisepticum*.

**HATCHERIES:** VIRKON-S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). VIRKON-S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.



**BROILER/BREEDER HOUSES:** Follow General Instructions above to remove poultry and preclean area to be treated. Spray floors and walls with VIRKON-S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of VIRKON-S (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus). After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

**FOR AIR SANITIZING:** Use VIRKON-S at 1-2% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

**PROCESSING PLANTS:** Spray VIRKON-S at 1% solution to disinfect and clean walls, ceilings and floors.

### SWINE [PRODUCTION]

**CONTROLS:** Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine Fever and Foot and Mouth Disease. Bacteria of Pleuropneumonia, Treponema hyodysenteriae, and Clostridium perfringens. Fungi: Fusarium moniliforme.

Follow General Instructions above to remove swine and preclean area to be treated. VIRKON-S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants (use a 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus), and agricultural production equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

VIRKON-S at 1-2% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

### EQUINE [PRODUCTION]

**BROAD SPECTRUM EQUINE DISINFECTANT/DETERGANT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION**

#### CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis. Bacterial: Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei



(Glanders). Fungi: Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), and *Fusarium moniliforme*.

**APPLICATIONS:** For cleaning and disinfecting all surfaces, equipment, utensils and instruments in Veterinary practices [, kennels, stables, catteries, etc].

**USES:**

Stables, [Horse Boxes, ][Box ]Stalls, Tack ,[Equipment,] and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% VIRKON-S solution. Rinse with clean water.

Blankets, [Saddle Pads] [and] Rugs: Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

Aerial Spraying to control airborne diseases: Use a hand [or knapsack] sprayer with fine setting, or an automatic spraying system. Spray a 1% VIRKON-S solution for 2-3 minutes twice daily [, first thing in the morning and last thing at night]. Rinse sprayers with water after use.

**BOVINE [PRODUCTION]**

**CONTROLS:** Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies and Foot and Mouth Disease; Bacteria of *Maraxella bovis*, *Haemophilus somnus* and *Mycobacterium bovis*; Fungi of *Fusarium moniliforme*.

Follow General Instructions above to remove livestock and preclean area to be treated. A 1% solution of VIRKON-S is recommended to clean and disinfect areas associated with bovine housing [stabling], hospital [quarantine] pens, feedlot facilities, and agricultural production equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

**COMPANION ANIMALS**

**CONTROLS:** Viruses Canine Parvovirus, Distemper, *Leptospira canicola*, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of *Staphylococcus aureus*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*; Fungi of *Microsporum canis*.

**[APPLICATIONS:]** A 1% solution of VIRKON-S is recommended as a "one step" cleaning and disinfecting procedure for all surfaces, equipment, instruments, utensils and cages [caging systems]within [associated with][Veterinary Medical Hospitals,] [infections disease wards,] [quarantine areas,] [Humane Society facilities,] [laboratory animal quarters,] grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in VIRKON-S for long periods - 10 minutes is maximum contact time.



## EMERGENCY DISEASE CONTROL

### CONTROLS: Foot and Mouse Disease Virus

A 1% solution of VIRKON-S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray VIRKON-S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in VIRKON-S for long periods - 10 minutes is maximum contact time.

### STORAGE AND DISPOSAL

**STORAGE:** Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

**DISPOSAL:** Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals



February 12, 2002

Mr. Adam Heyward, PM #34  
Antimicrobials Branch  
US EPA  
Washington, DC 20460

Subject: Virkon S; EPA Reg. No. 62432-1; Notification of Correction of Typographical Errors

Dear Adam:

Enclosed please find the following documents pursuant to a notification of the correction of typographical errors on the Virkon S label.

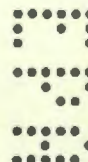
- Application for Pesticide Registration (EPA Form 8570-1)
- Proposed Product Label (5 copies with proposed changes highlighted)
- Current Stamped Label

Under normal circumstances, most, if not all of the proposed modifications would qualify for non-notification. Unfortunately some State reviewers now insist that even typographical changes be covered by an EPA notification. To expedite your review I have attached a short summary of the proposed changes.

Let me know if you have any questions regarding this submission or if I need to supply additional information. Thanks for your assistance.

Sincerely,

T. Jeffrey Jones, Agent  
Antec International Ltd.  
Enclosures

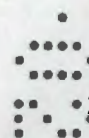
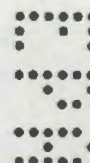




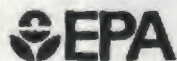
## Summary of Typographical Changes to the Virkon-S Label

### 12 February 2002

1. The value for "OTHER INGREDIENTS" has been changed from 77.1% to 78.1% to agree with the CSF and previous versions of the label. At 77.1% the total does not add to 100%.
2. In the Section titled "General Instructions," last unnumbered paragraph, third sentence. add the phrase "in VIRKON-S" after the word "objects."
3. In the section listing Swine Bacteria, change the spelling of "Treponema hyodysenteria" to "Treponema hyodysenteriae."
4. In the section listing Equine Viruses, change "Viral Arteritis" to "Equine Viral Arteritis."
5. In the section listing Companion Animal Bacteria, change "Streptococcus Aureus" to "Staphylococcus Aureus."







United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

258550

## Application for Pesticide - Section I

1. Company/Product Number 62432-1	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Virkon S	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd. c/o Delta Analytical Corp. 7910 Woodmont Ave., Suite 1000 Bethesda, MD 20814	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____  Product Name _____	
<input type="checkbox"/> Check if this is a new address		

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of correction of typographical and printing errors.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 USC Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Notification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Jeff Jones		Title Agent, Antec International Ltd.		Telephone No. (Include Area Code) 301 652 5495	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)  278
2. Signature 		3. Title Agent, Antec International Ltd.			
4. Typed Name Jeff Jones		5. Date 1 February 2002			



560635H

A. Whitaker

## CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 62432-1 PM 34 ACTION CODE 303

DESCRIPTOR Revised label in response to EPA's ltr dated 9/19/01

☐ CHILD RESISTANT PACKAGING: ☐ CERTIFICATION  
☐ NON-RESIDENTIAL USE ONLY  
☐ NOT APPLICABLE

REGISTRATION TYPE: ☐ CONDITIONAL ☐ UNCONDITIONALPROPOSED CLASSIFICATION: ☐ GENERAL ☐ RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

12 26 01

12 27 01

01 08 02

METHOD OF SUPPORT

FORMULATORS EXEMPTION

☐ CITE-ALL  
☐ SELECTIVE  
☐ NOT SUBMITTED  
☐ NOT APPLICABLE  
☐ INCORRECT/RESUB

☐ SUBMITTED  
☐ NOT SUBMITTED  
☐ NOT APPLICABLE  
☐ INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA  
PACK #DATE  
SENTDUE  
DATEDATE  
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

RESPONSE CODE

17

RESPONSE DATE

1/17/02





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

JAN 17 2002

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Mr. T. Jeffrey Jones, Agent  
Antec International Ltd.  
c/o Delta Analytical Corp.  
7910 Woodmont Avenue, Suit 1000  
Bethesda, MD 20814

Subject: Amendment to combine Farm Premises and Poultry House Directions  
Virkon S  
EPA Registration No. 62432-1  
Your Application Dated December 26, 2001

Dear Mr. Jones:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable.

Submit three (3) copies of the final printed labeling prior to releasing the product sale in the inter-state commerce.

A stamped copy is enclosed for your records.

If you have any questions concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely yours,

Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

Enclosure

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

280



**VIRKON-S®**  
**BROAD SPECTRUM DISINFECTANT**

**For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities**

**ACTIVE INGREDIENTS:**

Potassium peroxymonosulfate.....	20.4%
Sodium Chloride.....	1.5%
INERT INGREDIENTS.....	<u>77.1%</u>
TOTAL.....	100.00%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

**See Back [Side] Panel[s] for Additional Precautions**

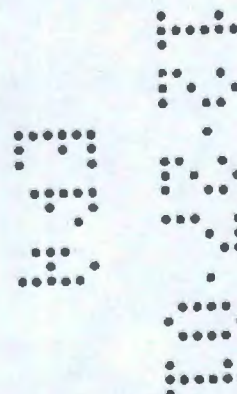
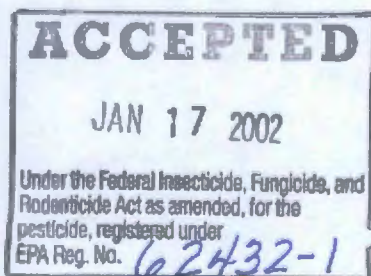
\_\_\_ lbs. (\_\_\_) Net Weight

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

**ANTEC INTERNATIONAL LTD.**  
Windham Road, Chilton Industrial Estates  
Sudbury Suffolk CO10 6XD, England  
Tel: (1787) 77305 Telex: 987495 Fax: (1787) 310846

**VIRKON S is a registered trademark of and manufactured by Antec International Limited**  
**US Patent No. 4822512**





# EFFECTIVE AGAINST:

## EQUINE BACTERIA

Clostridium perfringens  
Fistulous withers (Poll Evil)  
Taylorella equigenitalis  
Streptococcus equi (Strangles)  
Pseudomonas mallei  
(Glanders)  
Bordetella bronchiseptica

## EQUINE VIRUSES

African Horse Sickness  
African Viral Arteritis  
(Pink Eye)  
Coital Exanthema  
Myeloencephalopathy  
Rhinopneumonitis  
Equine Infectious Anemia  
(Swamp Fever)  
Equine papillomatosis  
Equine Contagious Abortion  
Adenovirus Pneumonia  
Equine Influenza (The Cough)

## EQUINE FUNGI

Trichophyton spp.  
(Ringworm)  
Trichophyton spp.  
(Mud Fever)  
Fusarium moniliforme

## BOVINE BACTERIA

Moraxella bovis  
Mycobacterium bovis  
Haemophilus somnus

## BOVINE VIRUSES

Calf rotavirus  
Infective Bovine  
Rhinotracheitis  
Bovine Adenovirus Type 4  
Pseudorabies  
Foot & Mouth Disease

## BOVINE FUNGI

Fusarium moniliforme

## POULTRY BACTERIA

Streptococcus pyogenes  
Campylobacter pyloridis  
Klebsiella pneumoniae  
Escherichia coli  
Salmonella typhimurium  
Salmonella choleae  
Pseudomonas aeruginosa  
Staphylococcus aureus  
Staphylococcus epidermidis  
Mycoplasma gallisepticum  
Clostridium perfringens  
Bordetella avium

## POULTRY VIRUSES

Newcastle Disease  
Infectious Bronchitis  
Infectious Bursal Disease  
Avian Laryngotracheitis  
Avian Influenza  
Marek's Disease  
Egg Drop Syndrome  
Adenovirus  
Turkey Herpes Virus  
Duck Herpes Virus  
Duck Viral Enteritis

## POULTRY FUNGI

Aspergillus flavus  
Aspergillus fumigatus  
Candida albicans

## SWINE BACTERIA

Bordetella bronchiseptica  
Pasteurella multocida  
Actinobacillus  
pleuropneumonia  
Treponema hyodysenteria  
Clostridium perfringens

## SWINE VIRUSES

Hog Cholera  
Swine Influenza  
Porcine parvovirus  
Rotaviral diarrhea  
Vesicular stomatitis  
Pseudorabies  
Porcine Reproductive and  
Respiratory Syndrome  
(PRRS)  
African Swine Fever  
Foot and Mouth Disease

## SWINE FUNGI

Fusarium moniliforme

## COMPANION ANIMALS BACTERIA

Streptococcus aureus  
Streptococcus pyogenes  
Klebsiella pneumoniae  
Pseudomonas aeruginosa

## VIRUSES

Canine Parvovirus  
Distemper  
Leptospira canicola  
Feline parvovirus  
Feline herpes  
Feline calicivirus

## FUNGI

Microsporium canis



**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
DANGER**

Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive statement refers to powder only not in use solution.

**FIRST AID**

**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention if irritation persists.

**IF INHALED:** If symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

**IF SWALLOWED:** Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

**NOTICE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

**BROAD SPECTRUM DISINFECTANT**

VIRKON-S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material. VIRKON-S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

**General Instructions—Poultry and Farm Premises**

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.

2. Remove all litter droppings and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.

3. Empty all troughs, racks, and other feeding and watering appliances.

4. Thoroughly clean all surfaces with soap or detergent and rinse with water.

5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.



6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.

8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

This powder formula is easily diluted for use in manual or machine operations.

#### ***VIRKON-S DILUTION CHART***

*Fill container with desired amount of water and add VIRKON-S powder to achieve recommended solution concentration.*

<i>Quantity of Water</i>	<i>Amount of Powder for 1% Solution</i>	<i>Amount of Powder for 2% Solution</i>
<i>1 Quart</i>	<i>0.3 ounces</i>	<i>0.7 ounces</i>
<i>1 Gallon</i>	<i>1.3 ounces</i>	<i>2.7 ounces</i>
<i>10 Gallons</i>	<i>13.4 ounces</i>	<i>26.7 ounces</i>
<i>50 Gallons</i>	<i>66.8 ounces</i>	<i>133.5 ounces</i>

*1.3 oz. measuring scoop is provided.*

Add [1.3 oz. (1 scoop) of VIRKON-S] [the contents of one VIRKON-S packet] to one gallon of warm water. Solutions are stable for 7 days. Do not soak metal objects for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

#### **POULTRY [AND RATITE PRODUCTION]**

**CONTROLS:** Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*. Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium* and *Mycoplasma gallisepticum*.

**HATCHERIES:** VIRKON-S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). VIRKON-S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.



**BROILER/BREEDER HOUSES:** Follow General Instructions above to remove poultry and preclean area to be treated. Spray floors and walls with VIRKON-S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of VIRKON-S (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus). After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

**FOR AIR SANITIZING:** Use VIRKON-S at 1-2% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

**PROCESSING PLANTS:** Spray VIRKON-S at 1% solution to disinfect and clean walls, ceilings and floors.

### SWINE [PRODUCTION]

**CONTROLS:** Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine Fever and Foot and Mouth Disease. Bacteria of Pleuropneumonia, Treponema hyodysenteriae, and Clostridium perfringens. Fungi: Fusarium moniliforme.

Follow General Instructions above to remove swine and preclean area to be treated. VIRKON-S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants (use a 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus), and agricultural production equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

VIRKON-S at 1-2% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

### EQUINE [PRODUCTION]

#### BROAD SPECTRUM EQUINE DISINFECTANT/DETERGANT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

##### CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis. Bacterial: Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei



(Glanders). Fungi: Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), and Fusarium moniliforme.

**APPLICATIONS:** For cleaning and disinfecting all surfaces, equipment, utensils and instruments in Veterinary practices [, kennels, stables, catteries, etc].

**USES:**

Stables, [Horse Boxes, ][Box ]Stalls, Tack ,[Equipment,] and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% VIRKON-S solution. Rinse with clean water.

Blankets, [Saddle Pads] [and] Rugs: Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

Aerial Spraying to control airborne diseases: Use a hand [or knapsack] sprayer with fine setting, or an automatic spraying system. Spray a 1% VIRKON-S solution for 2-3 minutes twice daily [, first thing in the morning and last thing at night]. Rinse sprayers with water after use.

**BOVINE [PRODUCTION]**

**CONTROLS:** Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies and Foot and Mouth Disease; Bacteria of Maraxella bovis, Haemophilus somnus and Mycobacterium bovis; Fungi of Fusarium moniliforme.

Follow General Instructions above to remove livestock and preclean area to be treated. A 1% solution of VIRKON-S is recommended to clean and disinfect areas associated with bovine housing [stabling], hospital [quarantine] pens, feedlot facilities, and agricultural production equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

**COMPANION ANIMALS**

**CONTROLS:** Viruses Canine Parvovirus, Distemper, Leptospira canicola, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa; Fungi of Microsporum canis.

[APPLICATIONS:] A 1% solution of VIRKON-S is recommended as a "one step" cleaning and disinfecting procedure for all surfaces, equipment, instruments, utensils and cages [caging systems]within [associated with][Veterinary Medical Hospitals,] [infections disease wards,] [quarantine areas,] [Humane Society facilities,] [laboratory animal quarters,] grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in VIRKON-S for long periods - 10 minutes is maximum contact time.



## EMERGENCY DISEASE CONTROL

### CONTROLS: Foot and Mouse Disease Virus

A 1% solution of VIRKON-S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray VIRKON-S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in VIRKON-S for long periods - 10 minutes is maximum contact time.

### STORAGE AND DISPOSAL

**STORAGE:** Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

**DISPOSAL:** Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals



December 26, 2001

Mr. Adam Heyward, PM #34  
Antimicrobials Branch  
US EPA  
Washington, DC 20460

Subject: Virkon S; EPA Reg. No. 62432-1; Amendment to Combine Directions for Use  
Text to Save Space

Dear Adam:

Enclosed please find the following documents in support of an amendment to the Virkon S label to combine directions for use text adapted from text requested in your letter of September 19, 2001.

- Application for Pesticide Registration (EPA Form 8570-1)
- Proposed Product Label (5 copies with proposed changes highlighted)
- Current Stamped Label

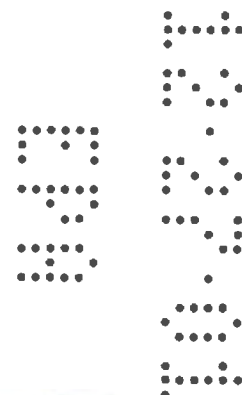
If you recall we discussed these changes by telephone and you approved combining the Farm Premises and Poultry House sections to save space as most of the text was identical in the two sections. You also agreed that it was advisable for me to resubmit the label for stamping to avoid confusion when the individual States receive copies of EPA-approved labels. As I am in the process of sending these labels to the States for annual renewals, I would appreciate your stamping and returning the label as soon as possible.

Let me know if you have any questions regarding this submission or if I need to supply additional information. Thanks for your assistance.

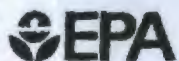
Sincerely,



T. Jeffrey Jones, Agent  
Antec International Ltd.  
Enclosures







United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

258548

## Application for Pesticide - Section I

1. Company/Product Number 62432-1	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Virkon S	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd. c/o Delta Analytical Corp. 7910 Woodmont Ave., Suite 1000 Bethesda, MD 20814		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____  Product Name _____
<input type="checkbox"/> Check if this is a new address		

## Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Proposed amendment to combine farm premises and poultry house directions for use. The proposed text was adapted from language requested by Mr. Heyward's letter of September 19, 2001.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
* Notification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Plastic	
		If "Yes" Package wgt	No. per container	<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Jeff Jones	Title Agent, Antec International Ltd.	Telephone No. (Include Area Code) 301 652 5495
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		Date Application Received (Stamped)    
2. Signature 	3. Title Agent, Antec International Ltd.	
4. Typed Name Jeff Jones	5. Date 26 December 2001	



SUBMISSION BAR CODE 5602936REVIEWER R. WhitakerCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 62432-1 PM 34 ACTION CODE 302DESCRIPTOR Labeling

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION  
[ ] NON-RESIDENTIAL USE ONLY  
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

8 28 018 29 019 4 01

METHOD OF SUPPORT

FORMULATORS EXEMPTION

[ ] CITE-ALL  
[ ] SELECTIVE  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

[ ] SUBMITTED  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA  
PACK #DATE  
SENTDUE  
DATEDATE  
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

RESPONSE CODE

17

RESPONSE DATE

9/09/01



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

SEP 19 2001

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Mr. T. Jeffrey Jones  
Delta Analytical Corporation, Agent for  
Antec International Ltd.  
7910 Woodmont Avenue, Suite 1000  
Bethesda, MD 20814

Subject: Amendment for Additional Use Sites  
Virkon S  
EPA Registration No.62432-1  
Amended Application Dated April 25, 2001

Dear Mr. Jones:

This letter acknowledges receipt of your application for amendment for adding additional use sites to the label.

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable with the following comments.

I. FARM PREMISES:

The following label directions are required for farm premises disinfectants to permit their classification as non-food use products:

Directions for Use

1. Do not use in milking stalls, milking parlors, or milk houses (for phenolics, cresylic acid, and pine oils).
2. Remove all animals and feed from premises, vehicles, and enclosures.
3. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

4. Empty all troughs, racks, and other feeding and watering appliances.
5. Thoroughly clean all surfaces with soap or detergent and rinse with water.
6. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
7. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
8. Ventilate buildings, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set, or dried.
9. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

## II. POULTRY HOUSE:

### Directions for Use

The following label directions are required for poultry house disinfectants to permit their classification as non-food use products:

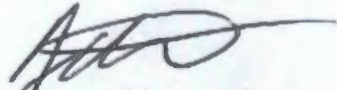
1. Remove all poultry and feeds from premises, trucks, coops, and crates.
2. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
7. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.



A stamped copy is enclosed for your records.

If you have any questions concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely yours,



Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

**VIRKON-S®**  
**BROAD SPECTRUM DISINFECTANT**

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities

**ACTIVE INGREDIENTS:**

Potassium peroxymonosulfate.....	20.4%
Sodium Chloride.....	1.5%
INERT INGREDIENTS.....	<u>77.1%</u>
TOTAL.....	100.00%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

See Back [Side] Panel[s] for Additional Precautions

\_\_\_ lbs. (\_\_\_) Net Weight

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

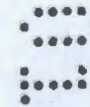
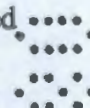
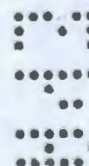
**ANTEC INTERNATIONAL LTD.**  
Windham Road, Chilton Industrial Estates  
Sudbury Suffolk CO10 6XD, England  
Tel: (1787) 77305 Telex: 987495 Fax: (1787) 310846

VIRKON S is a registered trademark of and manufactured by Antec International Limited  
US Patent No. 4822512

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

SEP 11 9 2001

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 62432-1





**EFFECTIVE AGAINST:**

**EQUINE BACTERIA**

Clostridium perfringens  
Fistulous withera (Poll Evil)  
Taylorella equigenitalis  
Streptococcus equi (Strangles)  
Pseudomonas mallei  
(Glanders)  
Bordetella bronchiseptica

**EQUINE VIRUSES**

African Horse Sickness  
African Viral Arteritis  
(Pink Eye)  
Coital Exanthema  
Myeloencephalopathy  
Rhinopneumonitis  
Equine Infectious Anemia  
(Swamp Fever)  
Equine papillomatosis  
Equine Contagious Abortion  
Adenovirus Pneumonia  
Equine Influenza (The Cough)

**EQUINE FUNGI**

Trichophyton spp. (Ringworm)  
Trichophyton spp.  
(Mud Fever)  
Fusarium moniliforme

**BOVINE BACTERIA**

Moraxella bovis  
Mycobacterium bovis  
Haemophilus somnus

**BOVINE VIRUSES**

Calf rotavirus  
Infective Bovine  
Rhinotracheitis  
Bovine Adenovirus Type 4  
Pseudorabies  
Foot & Mouth Disease

**BOVINE FUNGI**

Fusarium moniliforme

**POULTRY BACTERIA**

Streptococcus pyogenes  
Campylobacter pyloridis  
Klebsiella pneumoniae  
Escherichia coli  
Salmonella typhimurium  
Salmonella choleae  
Pseudomonas aeruginosa  
Staphylococcus aureus  
Staphylococcus epidermidis  
Mycoplasma gallisepticum  
Clostridium perfringens  
Bordetella avium

**POULTRY VIRUSES**

Newcastle Disease  
Infectious Bronchitis  
Infectious Bursal Disease  
Avian Laryngotracheitis  
Avian Influenza  
Marek's Disease  
Egg Drop Syndrome  
Adenovirus

Turkey Herpes Virus  
Duck Herpes Virus  
Duck Viral Enteritis

**POULTRY FUNGI**

Aspergillus flavus  
Aspergillus fumigatus  
Candida albicans

**SWINE BACTERIA**

Bordetella bronchiseptica  
Pasteurella multocida  
Actinobacillus  
pleuropneumonia  
Treponema hyodysenteria  
Clostridium perfringens

**SWINE VIRUSES**

Hog Cholera  
Swine Influenza  
Porcine parvovirus  
Rotaviral diarrhea  
Vesicular stomatitis  
Pseudorabies  
Porcine Reproductive and  
Respiratory Syndrome  
(PRRS)  
African Swine Fever  
Foot and Mouth Disease

**SWINE FUNGI**

Fusarium moniliforme

**COMPANION ANIMALS**

**BACTERIA**

Streptococcus aureus  
Streptococcus pyogenes  
Klebsiella pneumoniae  
Pseudomonas aeruginosa

**VIRUSES**

Canine Parvovirus  
Distemper  
Leptospira canicola  
Feline parvovirus  
Feline herpes  
Feline calicivirus

**FUNGI**

Microsporum canis

**ACCEPTED  
with COMMENTS  
in EPA Letter Dated:**

**SEP 19 2001**

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 62432-1



**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
DANGER**

Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive statement refers to powder only not in use solution.

**FIRST AID**

**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention if irritation persists.

**IF INHALED:** If symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

**IF SWALLOWED:** Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

**NOTICE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

**BROAD SPECTRUM DISINFECTANT**

VIRKON-S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material. VIRKON-S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.

**ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
SEP 19 2001**

**DIRECTIONS FOR USE**

Federal law prohibits use of this product in a manner inconsistent with its labeling

This powder formula is easily diluted for use in manual or machine operations.

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 62432-1

**VIRKON-S DILUTION CHART**

Fill container with desired amount of water and add VIRKON-S powder to achieve recommended solution concentration.

Quantity of Water	Amount of Powder for 1% Solution	Amount of Powder for 2% Solution
1 Quart	0.3 ounces	0.7 ounces
1 Gallon	1.3 ounces	2.7 ounces
10 Gallons	13.4 ounces	26.7 ounces
50 Gallons	66.8 ounces	133.5 ounces

1.3 oz. measuring scoop is provided.



Add [1.3 oz. (1 scoop) of VIRKON-S] [the contents of one VIRKON-S packet] to one gallon of warm water. Solutions are stable for 7 days. Do not soak metal objects for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

### POULTRY [AND RATITE PRODUCTION]

**CONTROLS:** Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*. Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium* and *Mycoplasma gallisepticum*.

**HATCHERIES:** VIRKON-S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). VIRKON-S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

**BROILER/BREEDER HOUSES:** Remove chickens [birds], feed, and water troughs, then remove manure and litter. Spray floors and walls with VIRKON-S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of VIRKON-S (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

**FOR AIR SANITIZING:** Use VIRKON-S at 1-2% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

**PROCESSING PLANTS:** Spray VIRKON-S at 1% solution to disinfect and clean walls, ceilings and floors.

### SWINE [PRODUCTION]

**CONTROLS:** Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine Fever and Foot and Mouth Disease. Bacteria of Pleuropneumonia, *Treponema hyodysenteriae*, and *Clostridium perfringens*. Fungi: *Fusarium moniliforme*.

VIRKON-S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants (use a 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*), and agricultural production equipment such as trucks, water-proof footwear (rubber boots), and associated livestock equipment and instruments.

ACCEPTED  
with COMMENTS  
in EPA Letter to Antec

SEP 19 2001



VIRKON-S at 1-2% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

### EQUINE [PRODUCTION]

#### BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

##### CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis. Bacterial: Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders). Fungi: Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), and Fusarium moniliforme.

APPLICATIONS: For cleaning and disinfecting all surfaces, equipment, utensils and instruments in Veterinary practices [, kennels, stables, catteries, etc].

##### USES:

Stables, [Horse Boxes, ][Box ]Stalls, Tack ,[Equipment,] and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% VIRKON-S solution. Rinse with clean water.

Blankets, [Saddle Pads] [and] Rugs: Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

Aerial Spraying to control airborne diseases: Use a hand [or knapsack] sprayer with fine setting, or an automatic spraying system. Spray a 1% VIRKON-S solution for 2-3 minutes twice daily [, first thing in the morning and last thing at night]. Rinse sprayers with water after use.

### BOVINE [PRODUCTION]

CONTROLS: Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies and Foot and Mouth Disease; Bacteria of Maraxella bovis, Haemophilus somnus and Mycobacterium bovis; Fungi of Fusarium moniliforme.

A 1% solution of VIRKON-S is recommended to clean and disinfect areas associated with bovine housing [stabling], hospital [quarantine] pens, feedlot facilities, and agricultural production equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

### COMPANION ANIMALS

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
SEP 13 2001



**CONTROLS:** Viruses Canine Parvovirus, Distemper, Leptospira canicola, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa; Fungi of Microsporium canis.

[APPLICATIONS:] A 1% solution of VIRKON-S is recommended as a "one step" cleaning and disinfecting procedure for all surfaces, equipment, instruments, utensils and cages [caging systems] within [associated with] [Veterinary Medical Hospitals,] [infections disease wards,] [quarantine areas,] [Humane Society facilities,] [laboratory animal quarters,] grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in VIRKON-S for long periods - 10 minutes is maximum contact time.

#### EMERGENCY DISEASE CONTROL

##### **CONTROLS:** Foot and Mouth Disease Virus

A 1% solution of VIRKON-S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment, airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, fillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray VIRKON-S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in VIRKON-S for long periods - 10 minutes is maximum contact time.

#### STORAGE AND DISPOSAL

**STORAGE:** Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

**DISPOSAL:** Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

SEP 19 2001

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 62432-1

c:\antec\Virkon S\label proposal 28 August 2001.wpd



August 28, 2001

Mr. Adam Heyward, PM #34  
Antimicrobials Branch  
US EPA  
Washington, DC 20460

Subject: Virkon S; EPA Reg. No. 62432-1; Amendment to Add Use Sites; State of North Carolina

Dear Adam:

Enclosed please find the following documents in support of an amendment to the Virkon S registration to add new use sites related to Foot and Mouth Disease Virus:

- Application for Pesticide Registration (EPA Form 8570-1)
- Proposed Product Label (5 copies)

The proposed amendatory language is highlighted. These use sites, gathered under the heading "Emergency Disease Control," were requested by Meg Scott Phipps, Commissioner of the North Carolina Department of Agriculture and Consumer Services in a letter to the Agency dated April 16, 2001 [attached]. I understand that Lee Davis of Ms. Phipps' staff has contacted you independently to discuss this request.

Let me know if you have any questions regarding this submission or if I need to supply additional information. Thanks for your assistance.

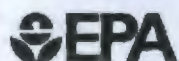
Sincerely,

T. Jeffrey Jones, Agent  
Antec International Ltd.  
Enclosures

cc: Jeff Kempter (cover by facsimile only)

7910 Woodmont Avenue Suite 1000 Bethesda, Maryland 20814  
(301) 652-5495 FAX (301) 652-5408





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

258542

## Application for Pesticide - Section I

1. Company/Product Number 62432-1	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Virkon S	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd. c/o Delta Analytical Corp. 7910 Woodmont Ave., Suite 1000 Bethesda, MD 20814	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
<input type="checkbox"/> Check if this is a new address		

## Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Proposed amendment to add use sites related to Foot and Mouth Disease Virus requested by the North Carolina Department of Agriculture and Consumer Services

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Notification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Jeff Jones	Title Agent, Antec International Ltd.	Telephone No. (Include Area Code) 301 652 5495
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.		6. Date Application Received (Stamped) ..... ..... ..... ..... .....
2. Signature Jeff Jones	3. Title Agent, Antec International Ltd.	
4. Typed Name Jeff Jones	5. Date 28 August 2001	



MEG SCOTT PHIPPS  
COMMISSIONER



State of North Carolina  
Department of Agriculture and Consumer Services  
Raleigh

April 16, 2001

Ms. Linda Gerber  
U.S. EPA / Office of Pesticide Programs  
Emergency Response Team (7505C)  
Document Processing Desk  
Crystal Mall 2 -- 2<sup>nd</sup> Floor  
1921 Jefferson Davis Hwy.  
Arlington, VA 22202

Dear Ms. Gerber,

This letter notifies the EPA that I am requesting the approval of a Quarantine Exemption under Section 18 of FIFRA to allow the use of several products as disinfectants for the control and eradication of Foot and Mouth Disease. The products to be used are listed in the following table.

Active Ingredient	Brand Name	EPA Reg. Number	Manufacturer
potassium peroxymonosulfate + sodium chloride	Virkon S	62432-1	Antec International
potassium peroxymonosulfate + sodium chloride	Virkon S	62432-1-270	Farnum Companies
potassium peroxymonosulfate + sodium chloride	Trifectant	62432-1-43591	Veterinary Products Laboratories
sodium hypochlorite	Any brand of bleach with up to 12.5% active ingredient.		
acetic acid	Any household vinegar with 4-5% acidity.		

The sites to which the above products can be applied include, but not limited to:

All sites on the labels of the EPA registered products, footwear, vehicles, agricultural facilities and equipment, military facilities and equipment, quarantine facilities and equipment, port facilities and equipment, shipping facilities and equipment, slaughter facilities and equipment.

As you know, Foot and Mouth is a devastating disease capable of causing catastrophic losses to any agricultural region it may infest. The spread of the disease throughout Europe and Great Britain has resulted in the destruction of hundreds of thousands of hogs, cattle, and sheep leaving much of the livestock industry in ruin. The threat of the spread of Foot and Mouth disease to this country is real and cannot be ignored. International travel, both civilian and military, provides almost daily opportunities for distribution to the United States. North Carolina has several military facilities as well as.

P. O. Box 27647 • RALEIGH, NORTH CAROLINA 27611

PHONE (919) 733-7125 • FAX (919) 733-1141 • EMAIL MEG.PHIPPS@NCHMAIL.NET



Ms. Linda Gerber  
Arlington, VA 22202

April 16, 2001  
Page 2

civilian air and sea ports that regularly interact with the European community. To better protect North Carolina's 1.7 billion-dollar livestock and dairy industry as well as the United States' agricultural industry as a whole, I am requesting the use of the above disinfectants under a quarantine exemption.

Please find enclosed a copy of a letter from Carl P. Bausch allowing North Carolina to reference data submitted to the EPA by USDA/APHIS to support the quarantine exemption in our state. Also enclosed are copies of the labeling that provide directions on how to effectively use the products when treating for this highly contagious disease.

Should you have any questions regarding this exemption, please contact Jim Burnette, Julie Haigler or Lee Davis of the NCDA&CS Pesticide Section at 919-733-3556. Your attention to this matter is appreciated.

Sincerely,

*Meg Scott Phipps*

Meg Scott Phipps  
Commissioner

cc: David Marshall, D.V.M., State Veterinarian  
N. David Smith, Asst. Commissioner  
Bruce E. Williams, Director, Food and Drug Protection Division  
Carl V. Tart, Director, Research Farms Division  
Sharron A. Woodall, Deputy Administrator, Pesticide Operations  
Gene Millsaps, President, Carolina/Virginia Dairy Products Association  
Neal Stamey, President, NC Cattleman's Association  
Bundy B. Plyler, Executive Director, NC Cattleman's Beef Council  
Richard McKellar, President, NC Dairy Foundation  
Norman Jordan, Jr., President, NC Dairy Producers Association  
Larry Wooten, President, NC Farm Bureau Federation  
Shirley Waggoner-Eisenman, President, NC Meat Goat Association  
Mickey Hudson, President, NC Meat Processors Association  
Don Butler, NC Pork Council  
Wiley Shore, President, Southeast United Dairy Industry Association  
Eubert Correll, President, United Herd Improvement Association  
James L. Oblinger, Ph.D., Dean, NCSU College of Agriculture and Life Sciences  
Kelly White, USDA APHIS  
David Meredith, NC State Grange

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

April 26, 2001

Mr. T. Jeffrey Jones, Agent  
Antec International Ltd.  
c/o Delta, Analytical Corp.  
7910 Woodmont Avenue, Suite 1000  
Bethesda, MD 20814

Dear Mr. Jones:

Subject: Amendment to Add Use Sites; State of Vermont  
Virkon S  
EPA Registration No.62432-1  
Your Amended Application Dated April 25, 2001

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records.

If you have any questions concerning this letter, please contact me at  
(703) 308-6422.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Adam Heyward".

Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								



**VIRKON-S®**  
**BROAD SPECTRUM DISINFECTANT**

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities

**ACTIVE INGREDIENTS:**

Potassium peroxymonosulfate..... 20.4%

Sodium Chloride..... 1.5%

**INERT INGREDIENTS..... 77.1%**

**TOTAL..... 100.00%**

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

See Back [Side] Panel[s] for Additional Precautions

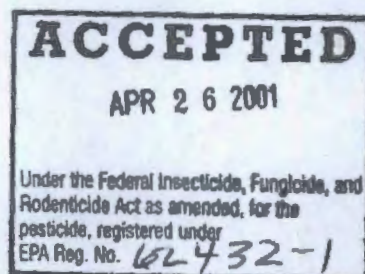
\_\_\_ lbs. (\_\_\_) Net Weight

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

**ANTEC INTERNATIONAL LTD.**  
Windham Road, Chilton Industrial Estates  
Sudbury Suffolk CO10 6XD, England  
Tel: (1787) 77305 Telex: 987495 Fax: (1787) 310846

**VIRKON S is a registered trademark of and manufactured by Antec International Limited**  
**US Patent No. 4822512**





**EFFECTIVE AGAINST:**

**EQUINE BACTERIA**

*Clostridium perfringens*  
*Fistulous withera* (Poll Evil)  
*Taylorella equigenitalis*  
*Streptococcus equi* (Strangles)  
*Pseudomonas mallei*  
(Glanders)  
*Bordetella bronchiseptica*

**EQUINE VIRUSES**

African Horse Sickness  
African Viral Arteritis  
(Pink Eye)  
Coital Exanthema  
Myeloencephalopathy  
Rhinopneumonitis  
Equine Infectious Anemia  
(Swamp Fever)  
Equine papillomatosis  
Equine Contagious Abortion  
Adenovirus Pneumonia  
Equine Influenza (The Cough)

**EQUINE FUNGI**

*Trichophyton* spp. (Ringworm)  
*Trichophyton* spp.  
(Mud Fever)  
*Fusarium moniliforme*

**BOVINE BACTERIA**

*Moraxella bovis*  
*Mycobacterium bovis*  
*Haemophilus somnus*

**BOVINE VIRUSES**

Calf rotavirus  
Infective Bovine  
Rhinothracheitis  
Bovine Adenovirus Type 4  
Pseudorabies  
Foot & Mouth Disease

**BOVINE FUNGI**

*Fusarium moniliforme*

**POULTRY BACTERIA**

*Streptococcus pyogenes*  
*Campylobacter pyloridis*  
*Klebsiella pneumoniae*  
*Escherichia coli*  
*Salmonella typhimurium*  
*Salmonella choleraesuis*  
*Pseudomonas aeruginosa*  
*Staphylococcus aureus*  
*Staphylococcus epidermidis*  
*Mycoplasma gallisepticum*  
*Clostridium perfringens*  
*Bordetella avium*

**POULTRY VIRUSES**

Newcastle Disease  
Infectious Bronchitis  
Infectious Bursal Disease  
Avian Laryngotracheitis  
Avian Influenza  
Marek's Disease  
Egg Drop Syndrome  
Adenovirus  
Turkey Herpes Virus  
Duck Herpes Virus  
Duck Viral Enteritis

**POULTRY FUNGI**

*Aspergillus flavus*  
*Aspergillus fumigatus*  
*Candida albicans*

**SWINE BACTERIA**

*Bordetella bronchiseptica*  
*Pasteurella multocida*  
*Actinobacillus*  
pleuropneumonia  
*Treponema hyodysenteria*  
*Clostridium perfringens*

**SWINE VIRUSES**

Hog Cholera  
Swine Influenza  
Porcine parvovirus  
Rotaviral diarrhea  
Vesicular stomatitis  
Pseudorabies  
Porcine Reproductive and  
Respiratory Syndrome  
(PRRS)  
African Swine Fever  
Foot and Mouth Disease

**SWINE FUNGI**

*Fusarium moniliforme*

**COMPANION ANIMALS**

**BACTERIA**

*Streptococcus aureus*  
*Streptococcus pyogenes*  
*Klebsiella pneumoniae*  
*Pseudomonas aeruginosa*

**VIRUSES**

Canine Parvovirus  
Distemper  
*Leptospira canicola*  
Feline parvovirus  
Feline herpes  
Feline calicivirus

**FUNGI**

*Microsporum canis*



**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
DANGER**

Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive statement refers to powder only not in use solution.

**FIRST AID**

**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention if irritation persists.

**IF INHALED:** If symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

**IF SWALLOWED:** Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

**NOTICE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

**BROAD SPECTRUM DISINFECTANT**

VIRKON-S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material. *VIRKON-S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.*

**DIRECTIONS FOR USE**

Federal law prohibits use of this product in a manner inconsistent with its labeling

This powder formula is easily diluted for use in manual or machine operations.

**VIRKON-S DILUTION CHART**

*Fill container with desired amount of water and add VIRKON-S powder to achieve recommended solution concentration.*

<i>Quantity of Water</i>	<i>Amount of Powder for 1% Solution</i>	<i>Amount of Powder for 2% Solution</i>
<i>1 Quart</i>	<i>0.3 ounces</i>	<i>0.7 ounces</i>
<i>1 Gallon</i>	<i>1.3 ounces</i>	<i>2.7 ounces</i>
<i>10 Gallons</i>	<i>13.4 ounces</i>	<i>26.7 ounces</i>
<i>50 Gallons</i>	<i>66.8 ounces</i>	<i>133.5 ounces</i>

*1.3 oz. measuring scoop is provided.*



**Add [1.3 oz. (1 scoop) of VIRKON-S] [the contents of one VIRKON-S packet] to one gallon of warm water. Solutions are stable for 7 days. Do not soak metal objects for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.**

## POULTRY [AND RATITE PRODUCTION]

**CONTROLS:** Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*. Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium* and *Mycoplasma gallisepticum*.

**HATCHERIES:** VIRKON-S at 1% solution *can be used* for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). VIRKON-S at 1-2% solution is recommended for use in fogging (wet misting) operations as a *supplemental measure*, either *before or after* regular cleaning and *disinfecting* procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

**BROILER/BREEDER HOUSES:** *Remove chickens [birds], feed, and water troughs, then remove manure and litter. Spray floors and walls with VIRKON-S at 1% solution.* Thoroughly wash waterers and feeders with a 1% solution of VIRKON-S (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). *After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.*

**FOR AIR SANITIZING:** Use VIRKON-S at 1-2% solution, *and fog until* surfaces are moist. Allow at least 2 hours before entering *treated area*. *Rinse foggers and sprayers with water following use.*

**PROCESSING PLANTS:** *Spray VIRKON-S at 1% solution to disinfect and clean walls, ceilings and floors.*

## SWINE [PRODUCTION]

**CONTROLS:** Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine Fever and Foot and Mouth Disease. Bacteria of *Pleuropneumonia*, *Treponema hyodysenteriae*, and *Clostridium perfringens*. Fungi: *Fusarium moniliforme*.

VIRKON-S at 1% solution is recommended for *cleaning and disinfecting* farrowing units, nurseries, finisher houses, processing plants (use a 2% solution for *Mycoplasma*, *Aspergillus flavus*



and *Aspergillus fumigatus*), and agricultural production equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

VIRKON-S at 1-2% solution is recommended for use in fogging (wet misting) operations or as a *supplemental measure* either *before* or *after* regular cleaning and *disinfecting* procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. *Rinse foggers and sprayers with water following use.*

### EQUINE [PRODUCTION]

#### BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

##### CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis. Bacterial: Clostridial Diarrhea, Fistulous Withers (Poll Evil), *Taylorella equigenitalis*, *Bordetella bronchiseptica*, *Streptococcus equi* (Strangles) and *Pseudomonas mallei* (Glanders). Fungi: Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), and *Fusarium moniliforme*.

APPLICATIONS: For cleaning and *disinfecting* all surfaces, equipment, utensils and instruments in Veterinary practices [, kennels, stables, catteries, etc].

##### USES:

Stables, [Horse Boxes, ][Box ]Stalls, Tack [,Equipment,] and Feed Rooms: Thoroughly *clean and dry* [dry clean] *surfaces*, then wash the area manually or with pressure washer with a 1% VIRKON-S solution. Rinse with clean water.

Blankets, [Saddle Pads] [and] Rugs: Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

Aerial Spraying to control airborne diseases: *Use a hand [or knapsack] sprayer with fine setting*, or an *automatic* spraying system. Spray a 1% VIRKON-S solution for 2-3 minutes twice daily [, first thing in the morning and last thing at night]. *Rinse sprayers with water after use.*

### BOVINE [PRODUCTION]

CONTROLS: Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies and Foot and Mouth Disease; Bacteria of *Maraxella bovis*, *Haemophilus somnus* and *Mycobacterium bovis*; Fungi of *Fusarium moniliforme*.

A 1% solution of VIRKON-S is recommended to *clean and disinfect* areas associated with bovine housing [stabling], hospital [quarantine] pens, feedlot facilities, and agricultural production



equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

### COMPANION ANIMALS

**CONTROLS:** Viruses Canine Parvovirus, Distemper, Leptospira canicola, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa; Fungi of Microsporum canis.

**[APPLICATIONS:]** *A 1% solution of VIRKON-S* is recommended as a "one step" cleaning and *disinfecting* procedure for all surfaces, equipment, instruments, utensils and *cages* [caging systems] within [associated with] [Veterinary Medical Hospitals,] [infections disease wards,] [quarantine areas,] [Humane Society facilities,] [laboratory animal quarters,] grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in VIRKON-S for long periods - 10 minutes is maximum contact time.

### STORAGE AND DISPOSAL

**STORAGE:** Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

**DISPOSAL:** Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals



# **ULTRASONIC BATH DISINFECTANT DIRECTIONS:**

Use LONZA FORMULATION R-82F to disinfect hard nonporous noncritical objects compatible with Ultrasonic cleaning units. Pour fresh solution of ½ oz. of Lonza Formulation R-82F per gallon of water (1:256) directly into bath chamber. Pre-clean heavily soiled objects. Place objects into unit and operate for a minimum of 10 minutes, according to the manufacturer's directions. Remove objects and wash with sterile water (sterile water for injection) or allow to air dry. Prepare fresh solution for each use.

# **SANITIZING NON-FOOD CONTACT SURFACE DIRECTIONS:**

Add (mix) ½ oz. per 4 gallons of water to sanitize hard nonporous surfaces. Treated surfaces must remain wet for 60 seconds.

**SANITIZING FOOD CONTACT SURFACES:** Use ½ oz. Lonza Formulation R-82F per 4 - 5 ½ gallons of water (200 - 150 ppm) for sanitizing and cleaning of equipment and utensils in food processing, dairy industry, bars, restaurants, institutional kitchens, meat and poultry processing plants and farms. Do not rinse with water.

For heavily soiled equipment or utensils, pre-wash with Lonza Formulation R-82F. Rinse with clean water then apply recommended dilution of Lonza Formulation R-82F with a cloth, coarse mechanical spray device (spray surface until thoroughly wetted) or immersion. Treated surfaces must remain wet for one minute. Prepare a fresh solution for every use. DO NOT reuse mechanically applied use solution for sanitizing. Lonza Formulation R-82F can be used in accordance with the U.S. Public Health Service food service sanitization recommendations.

## **U.S. PUBLIC HEALTH SERVICE FOOD SERVICE SANITIZATION RECOMMENDATIONS**

**CLEANING AND SANITIZING:** Equipment and utensils shall be thoroughly pre-flushed or pre-scraped and when necessary, pre-soaked to remove gross food particles and soil.

1. Thoroughly wash equipment and utensils in hot detergent solution.
2. Rinse utensils and equipment thoroughly with clean water.
3. Sanitize equipment and utensils by immersion in a ½ oz. per 4 - 5 ½ gallon solution of Lonza Formulation R-82F (200 - 150 ppm active) for at least 60 seconds at a temperature of 75°F.
4. For equipment and utensils too large to sanitize by immersion, apply a ½ oz. per 4 - 5 ½ gallon solution of Lonza Formulation R-82F (200 - 150 ppm active) by rinsing, spraying or swabbing until thoroughly wetted.
5. Allow sanitized surface to drain and air dry. Do not rinse

# **POULTRY AND SWINE PREMISE DISINFECTION DIRECTIONS:**

Remove all animals and feeds from premises, vehicles, and enclosures such as coops and crates. Remove all litter, droppings and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Use ½ oz. of LONZA FORMULATION R-82F per gallon of water. Saturate surfaces with the recommended disinfecting solution for 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings, cars, trucks, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

**HATCHERIES:** Use ½ oz. of LONZA FORMULATION R-82F per gallon of water to treat the following hard nonporous surfaces: hatching, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces wet for 10 minutes or more. Then allow to air dry.

**VEHICLES:** Clean all vehicles including mats, crates, cabs and wheels with high pressure water and LONZA FORMULATION R-82F. Use ½ oz. of LONZA FORMULATION R-82F per gallon of water to treat all vehicles. Leave all treated surfaces wet for 10 minutes or more.

**SHOE BATH SANITIZER DIRECTIONS:** To prevent tracking harmful organisms into animal areas, shoe baths containing one inch of freshly made solution should be placed at all entrances to buildings and hatcheries. Scrape waterproof work boots and place in a ½ oz. per 4 gallons of water solution for 60 seconds prior to entering area. Change the solution in the bath daily or more often if solution appears diluted or soiled.

**DRESSING PLANT DISINFECTANT DIRECTIONS:** Disinfect equipment, utensils, walls and floors in poultry and animal dressing plants. Disinfect offal rooms, exterior walls and loading platforms of dressing plants. Cover or remove all food and packaging materials. Remove all heavy soils prior to application. Saturate all surfaces with a ½ oz. of Lonza Formulation R-82F per gallon of water solution. Scrub to loosen all soils. Surfaces must remain wet for 10 minutes, then thoroughly rinsed with potable water before operations are resumed.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

DEC 14 2000

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended for the pesticide,





April 25, 2001

Mr. Jeff Kempter, Senior Adviser  
Antimicrobial Division, OPP  
US EPA  
Washington, DC 20460

Subject: Virkon S; EPA Reg. No. 62432-1; Amendment to Add Use Sites; State of Vermont

Dear Jeff:

Following up on our telephone conversation this morning, enclosed please find the following documents in support of an amendment to the Virkon S registration:

- Application for Pesticide Registration (EPA Form 8570-1)
- Proposed Product Label (5 copies)

The proposed amendatory language is highlighted. I understand the text has been previously discussed with Phil Benedict of the Vermont Department of Agriculture.

Please note that the proposed label also changes the percent active ingredient from the current stamped label. This change was recently requested during reregistration, but as yet we have not received the stamped label incorporating it. You may want to discuss this matter with Veronica Dutch or Maria Piansay.

Let me know if you have any questions regarding this submission or if I need to supply additional information. Thanks for your assistance.

Sincerely,

A handwritten signature in dark ink, appearing to read "Jeff", with a stylized flourish at the end.

T. Jeffrey Jones, Agent  
Antec International Ltd.  
Enclosures

7910 Woodmont Avenue Suite 1000 Bethesda, Maryland 20814  
(301) 652-5495 FAX (301) 652-5408



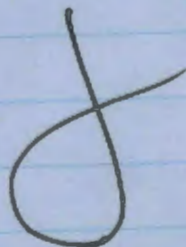
4/25/01

Jeff —

Replacement version  
based on conversation  
@ ~ 1:30 p.m. today.

Best regards,

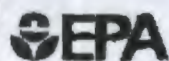
W





Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 2-28-95



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

258537

## Application for Pesticide - Section I

1. Company/Product Number  
62432-1

2. EPA Product Manager  
Adam Hayward

3. Proposed Classification

☒ None ☐ Restricted

4. Company/Product (Name)  
Virkon S

PM#  
#34

5. Name and Address of Applicant (Include ZIP Code)  
Antec International Ltd. c/o Delta Analytical Corp.  
7910 Woodmont Ave., Suite 1000  
Bethesda, MD 20814

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(ii), my product is similar or identical in composition and labeling to:

EPA Reg. No. \_\_\_\_\_

Product Name \_\_\_\_\_

☐ Check if this is a new address

## Section - II

☒ Amendment - Explain below.

☐ Resubmission in response to Agency letter dated \_\_\_\_\_

☐ Notification - Explain below.

☐ Final printed labels in response to  
Agency letter dated \_\_\_\_\_

☐ "Me Too" Application.

☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment to add new use sites: trucks, water-resistant footwear and associated equipment and instruments.

## Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging

☐ Yes  
☐ No

Unit Packaging

☐ Yes  
☐ No

Water Soluble Packaging

☐ Yes  
☐ No

2. Type of Container

☐ Metal  
☐ Plastic  
☐ Glass  
☐ Paper  
☐ Other (Specify) \_\_\_\_\_

Notification must  
be submitted

If "Yes"  
Unit Packaging wgt.

No. per  
container

If "Yes"  
Package wgt

No. per  
container

3. Location of Net Contents Information

☒ Label

☐ Container

4. Size(s) Retail Container

5. Location of Label Directions

☐

6. Manner in Which Label is Affixed to Product

☐ Lithograph  
Paper glued  
Standard

☐ Other \_\_\_\_\_

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name  
Jeff Jones

Title  
Agent, Antec International Ltd.

Telephone No. (Include Area Code)  
301 652 5495

## Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application  
Received  
(Stamped)

2. Signature

Jeff Jones

3. Title

Agent, Antec International Ltd.

4. Typed Name  
Jeff Jones

5. Date

25 APR 2001



[ ] indicates optional language

Page 1

**VIRKON-S<sup>®</sup>**  
**BROAD SPECTRUM DISINFECTANT**

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities

**ACTIVE INGREDIENTS:**Potassium peroxymonosulfate.....~~21.42~~%

Sodium Chloride.....1.50%

INERT INGREDIENTS.....77.08%

TOTAL.....100.00%

*Not now!*

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN****DANGER****See Back [Side] Panel[s] for Additional Precautions**

\_\_\_ lbs. (\_\_\_) Net Weight

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

**ANTEC INTERNATIONAL LTD.**  
Windham Road, Chilton Industrial Estates  
Sudbury Suffolk CO10 6XD, England  
Tel: (1787) 77305 Telex: 987495 Fax: (1787) 310846**VIRKON S** is a registered trademark of and manufactured by Antec International Limited  
US Patent No. 4822512



[ ] indicates optional language

Page 2

**EFFECTIVE AGAINST:****EQUINE BACTERIA**

*Clostridium perfringens*  
*Fistulous withera* (Poll Evil)  
*Taylorella equigenitalis*  
*Streptococcus equi* (Strangles)  
*Pseudomonas mallei*  
 (Glanders)  
*Bordetella bronchiseptica*

**EQUINE VIRUSES**

African Horse Sickness  
 African Viral Arteritis  
 (Pink Eye)  
*Coital Exanthema*  
*Myeloencephalopathy*  
*Rhinopneumonitis*  
*Equine Infectious Anemia*  
 (Swamp Fever)  
*Equine papillomatosis*  
*Equine Contagious Abortion*  
*Adenovirus Pneumonia*  
*Equine Influenza* (The Cough)

**EQUINE FUNGI**

*Trichophyton* spp. (Ringworm)  
*Trichophyton* spp.  
 (Mud Fever)  
*Fusarium moniliforme*

**BOVINE BACTERIA**

*Moraxella bovis*  
*Mycobacterium bovis*  
*Haemophilus somnus*

**BOVINE VIRUSES**

Calf rotavirus  
 Infective Bovine  
 Rhinotracheitis  
 Bovine Adenovirus Type 4  
*Pseudorabies*  
 Foot & Mouth Disease

**BOVINE FUNGI**

*Fusarium moniliforme*

**POULTRY BACTERIA**

*Streptococcus pyogenes*  
*Campylobacter pyloridis*  
*Klebsiella pneumoniae*  
*Escherichia coli*  
*Salmonella typhimurium*  
*Salmonella choleraesuis*  
*Pseudomonas aeruginosa*  
*Staphylococcus aureus*  
*Staphylococcus epidermidis*  
*Mycoplasma gallisepticum*  
*Clostridium perfringens*  
*Bordetella avium*

**POULTRY VIRUSES**

Newcastle Disease  
 Infectious Bronchitis  
 Infectious Bursal Disease  
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 Avian Influenza  
 Marek's Disease  
 Egg Drop Syndrome  
 Adenovirus  
 Turkey Herpes Virus  
 Duck Herpes Virus  
 Duck Viral Enteritis

**POULTRY FUNGI**

*Aspergillus flavus*  
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*Candida albicans*

**SWINE BACTERIA**

*Bordetella bronchiseptica*  
*Pasteurella multocida*  
*Actinobacillus*  
*pleuropneumonia*  
*Treponema hyodysenteria*  
*Clostridium perfringens*

**SWINE VIRUSES**

Hog Cholera  
 Swine Influenza  
 Porcine parvovirus  
 Rotaviral diarrhea  
 Vesicular stomatitis  
*Pseudorabies*  
 Porcine Reproductive and  
 Respiratory Syndrome  
 (PRRS)  
 African Swine Fever  
 Foot and Mouth Disease

**SWINE FUNGI**

*Fusarium moniliforme*

**COMPANION ANIMALS****BACTERIA**

*Streptococcus aureus*  
*Streptococcus pyogenes*  
*Klebsiella pneumoniae*  
*Pseudomonas aeruginosa*

**VIRUSES**

Canine Parvovirus  
 Distemper  
*Leptospira canicola*  
 Feline parvovirus  
 Feline herpes  
 Feline calicivirus

**FUNGI**

*Microsporum canis*



[ ] indicates optional language

Page 3

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
DANGER**

Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive statement refers to powder only not in use solution.

**FIRST AID**

**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention if irritation persists.

**IF INHALED:** If symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

**IF SWALLOWED:** Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

**NOTICE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

**BROAD SPECTRUM DISINFECTANT**

VIRKON-S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material. *VIRKON-S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.*

**DIRECTIONS FOR USE**

Federal law prohibits use of this product in a manner inconsistent with its labeling

This powder formula is easily diluted for use in manual or machine operations.

**VIRKON-S DILUTION CHART**

*Fill container with desired amount of water and add VIRKON-S powder to achieve recommended solution concentration.*

<i>Quantity of Water</i>	<i>Amount of Powder for 1% Solution</i>	<i>Amount of Powder for 2% Solution</i>
<i>1 Quart</i>	<i>0.3 ounces</i>	<i>0.7 ounces</i>
<i>1 Gallon</i>	<i>1.3 ounces</i>	<i>2.7 ounces</i>
<i>10 Gallons</i>	<i>13.4 ounces</i>	<i>26.7 ounces</i>
<i>50 Gallons</i>	<i>66.8 ounces</i>	<i>133.5 ounces</i>

*1.3 oz. measuring scoop is provided.*



[ ] indicates optional language

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**Add [1.3 oz. (1 scoop) of VIRKON-S] [the contents of one VIRKON-S packet] to one gallon of warm water. Solutions are stable for 7 days. Do not soak metal objects for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.**

### POULTRY [AND RATITE PRODUCTION]

**CONTROLS:** Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*. Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium* and *Mycoplasma gallisepticum*.

**HATCHERIES:** VIRKON-S at 1% solution *can be used* for cleaning and disinfecting hatchers, settlers, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). VIRKON-S at 1-2% solution is recommended for use in fogging (wet misting) operations as a *supplemental measure*, either *before or after* regular cleaning and *disinfecting* procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

**BROILER/BREEDER HOUSES:** *Remove chickens [birds], feed, and water troughs, then remove manure and litter. Spray floors and walls with VIRKON-S at 1% solution.* Thoroughly wash watercrs and feeders with a 1% solution of VIRKON-S (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). *After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.*

**FOR AIR SANITIZING:** Use VIRKON-S at 1-2% solution, *and fog until* surfaces are moist. Allow at least 2 hours before entering *treated area. Rinse foggers and sprayers with water following use.*

**PROCESSING PLANTS:** *Spray VIRKON-S at 1% solution to disinfect and clean walls, ceilings and floors.*

### SWINE [PRODUCTION]

**CONTROLS:** Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine **Fever** and Foot and Mouth Disease. Bacteria of Pleuropneumonia, *Treponema hyodysenteriae*, and *Clostridium perfringens*. Fungi: *Fusarium moniliforme*.

VIRKON-S at 1% solution is recommended for *cleaning and disinfecting* farrowing units, nurseries, finisher houses, processing plants (use a 2% solution for *Mycoplasma*, *Aspergillus flavus*



[ ] indicates optional language

Page 5

and *Aspergillus fumigatus*), and ~~and agriculture production equipment, feed, tack, and associated footwear, and associated livestock, equipment and instruments.~~

**VIRKON-S at 1-2% solution** is recommended for use in fogging (wet misting) operations or as a *supplemental measure* either *before* or *after* regular cleaning and *disinfecting* procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. *Rinse foggers and sprayers with water following use.*

### EQUINE [PRODUCTION]

#### BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

##### CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis. Bacterial: Clostridial Diarrhea, Fistulous Withers (Poll Evil), *Taylorella equigenitalis*, *Bordetella bronchiseptica*, *Streptococcus equi* (Strangles) and *Pseudomonas mallei* (Glanders). Fungi: Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), and *Fusarium moniliforme*.

**APPLICATIONS:** For cleaning and *disinfecting* all surfaces, equipment, utensils and instruments in Veterinary practices [, kennels, stables, catteries, etc].

##### USES:

Stables, [Horse Boxes, ][Box ]Stalls, Tack ,[Equipment,] and Feed Rooms: Thoroughly *clean and dry* [dry clean] *surfaces*, then wash the area manually or with pressure washer with a 1% VIRKON-S solution. *Rinse with clean water.*

Blankets, [Saddle Pads] [and] Rugs: Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

Aerial Spraying to control airborne diseases: *Use a hand [or knapsack] sprayer with fine setting*, or an *automatic* spraying system. *Spray a 1% VIRKON-S solution for 2-3 minutes twice daily [, first thing in the morning and last thing at night]. Rinse sprayers with water after use.*

### BOVINE [PRODUCTION]

**CONTROLS:** Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies ~~and Bovine and Human Herpes~~; Bacteria of *Maraxella bovis*, *Haemophilus somnus* and *Mycobacterium bovis*; Fungi of *Fusarium moniliforme*.

*A 1% solution of VIRKON-S is recommended to clean and disinfect areas associated with bovine housing [stabling], hospital [quarantine] pens, feedlot facilities, and agricultural production*



[ ] indicates optional language

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*proof (such as rubber boots)*  
~~contaminated as trucks, water, garbage, footwear, and associated livestock equipment and instruments.~~

### COMPANION ANIMALS

**CONTROLS:** Viruses Canine Parvovirus, Distemper, Leptospira canicola, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa; Fungi of Microsporum canis.

**[APPLICATIONS:]** A 1% solution of VIRKON-S is recommended as a "one step" cleaning and *disinfecting* procedure for all surfaces, equipment, instruments, utensils and *cages* [caging systems] within [associated with] [Veterinary Medical Hospitals,] [infectious disease wards,] [quarantine areas,] [Humane Society facilities,] [laboratory animal quarters,] grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in VIRKON-S for long periods - 10 minutes is maximum contact time.

### STORAGE AND DISPOSAL

**STORAGE:** Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

**DISPOSAL:** Wash empty container thoroughly and *dispose in trash*. *Do not mix this product with other chemicals*



file in jacket  
62432-1 3/19/98  
212  
~~re-submittal~~

Reviewer ID

Submission No.

Data Package No.

L. Dobbin's  
5530694  
239385

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No.

62432-1 PM 34

Action Code

308

[10] Descriptor (Amend/Resubmissions only)

Label Revision

[5] Intrastate Call-in ☐ (Y) Yes

☐ (N) No

[15] Child-resistant Packaging

☐ (C) Certification

☐ (S) Service Person

[20] Registration Type:

☒ (1) Conditional

☐ (2) Unconditional

☐ (R) Non-residential Use Only

☐ (N) Not-Applicable

[25] Proposed Classification:

[30] Final Classification:

☐ (R) Restricted

☐ (R) Restricted

☐ (G) General

☐ (N) Not Classified

[35] Date on Application:

MO DAY YR  
09 23 97

[04] EPA Received Date:

MO DAY YR  
09 26 97

[40] Date Received by PM

MO DAY YR  
09 30 97

[80] Method of Support:

☐ (1) Cite-All

☐ (6) Owner Submission

☐ (4) Not Applicable

☐ (7) Total Submission

☐ (5) Not Submitted

☐ (8) Selective Method

Reviewers Requested:

CH

EP

PL

DEB

NDEB

TB

EEB

EFGB

DATE SENT

DUE DATE

DATE RETURNED

RESPONSE CODE

RESPONSE DATE

9/26/97	1/14/98	3/19/98		

[115] FINAL Response ACTION Code

13

[120] Response:

MAR 19 1998

75-DAY RESPONSE DUE DATE: ☐ (Y) Yes

☐ (N) No

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 19 1998

Antec International Ltd  
c/o Farnam Companies, Inc.  
301 West Osborn  
Phoenix, AZ 85013

Attention: Dr. Douglas H. Ross  
Agent

Subject: Virkon S  
EPA Registration Number 62432-1  
Your Submission Dated September 26, 1997

In response to your submission of September 26, 1997 regarding the proposed labeling changes for the above product, the following comments apply.

The proposed label, EPA pinpunched October 1, 1997, is unacceptable for the following reasons:

1. The labeling claims against *Bacillus cereus*, *Bacillus subtilis*, *Campylobacter jejuni*, *Chlamydia psittaci*, *Erysipelothrix rhusiopathiae*, *Listeria monocytogenes*, *Pasteurella hemolytica*, *Salmonella enteritidis*, *Shigella sonnei*, and Parainfluenza virus, are all human health related microorganisms and require the submission of efficacy data to support the claims.
2. If you wish to make claims against *Bacillus* sp spores, the data must be developed in accordance with the DIS/TSS-9 enclosure, which outlines the data requirements for sporicidal products.
3. All other claims against vegetative bacteria and viruses, you must submit data in accordance with the DIS/TSS 1, 2, 3 and 7 enclosures.
4. Until the required data has been submitted to support the label claims against the microorganisms listed in number 1 above, those microorganisms must be removed from the label.

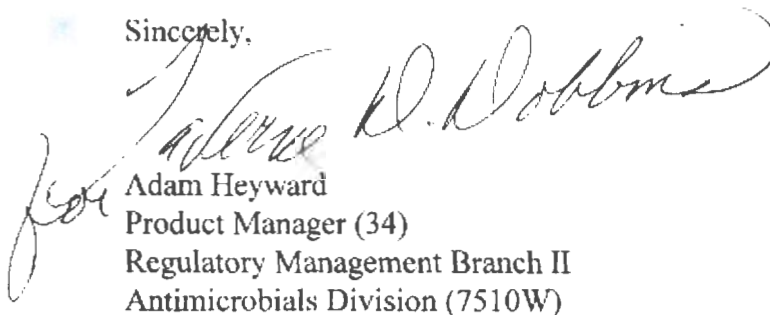
CONCURRENCES							
SYMBOL							
SURNAME							
DATE							



For further review of the labeling results, please refer to the Efficacy Evaluation dated March 19, 1998.

If you have further questions, please contact Michelle Wingfield at (703) 308-6349 or LaVerne Dobbins at (703) 308-6378.

Sincerely,



Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510W)

Enclosures: DIS/TSS(s) 1, 2, 3, 7 and 9

RISK ASSESSMENT & SCIENCE SUPPORT BRANCH

TEAM 2 - EFFICACY EVALUATION

ANTIMICROBIALS DIVISION

Date EPA Rec'd: 09/26/97 Date EET Rec'd: 09/29/97

Project Return Date: 3/25/98 Review Start Date: 3/19/98

Review Completion Date: 3/19/98

Reviewed By: Michele E. Wingfield, Microbiologist *Michele E. Wingfield*

LAN Code: 62432-1.398

EPA Reg. No. or File Symbol: 62432-1

EPA Petition or EUP No.: None

Product Name: Virkon S

Company Name: Antec International LTD

Product Type: Disinfectant

Product Formulation: Liquid to be diluted prior to use

Product Manager & Team No.: Adam Heyward PM-34 (L. Dobbins)

MRID No(s): None

Submission Purpose: Label review for clarification of efficacy requirements.

<u>ACTIVE INGREDIENT(S)</u>	<u>%</u>
Potassium peroxymonosulfate . . . . .	20.4%
Sodium chloride . . . . .	1.5%

**RECOMMENDATION:**

The proposed label, EPA pinpunched 10/1/97, is unacceptable for the following reasons:

1. The labeling claims against *Bacillus cereus*, *Bacillus subtilis*, *Camplobacter jejuni*, *Chlamydia psittaci*, *Erysipelothrix rhusiopathiae*, *Listeria monocytogenes*, *Pasteurella hemolytica*, *Salmonella enteritidis*, *Shigella sonnei*, and Parainfluenza virus,



are all human health related microorganisms and require the submission of efficacy data to support the claims.

2. If the registrant wishes to make claims against *Bacillus* sp spores, the data must be developed in accordance with the DIS/TSS-9 enclosure, which outlines the data requirements for sporicidal products.

3. All other claims against vegetative bacteria and viruses, must submit data in accordance with the DIS/TSS 1,2, and 7 enclosures.

4. Until the required data has been submitted to support the label claims against the microorganisms listed in number 1 above, those microorganisms must be removed from the label.

DIS/TSS-1 Jan 22, 1982  
EFFICACY DATA REQUIREMENTS

Disinfectants for Use on Hard Surfaces

- (a) Limited efficacy claims. The label of a disinfectant which is effective against a specific major group of microorganisms only (e.g., Grampositive or Gram-negative) must specify the major group against which it is effective.
- (1) Test requirements. The AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products) is required. Sixty carriers must be tested with each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against Salmonella choleraesuis ATCC 10708 (for effectiveness against Gram-negative bacteria) or Staphylococcus aureus ATCC 6538 (for effectiveness against Gram-positive bacteria). (Sixty carriers per sample; a total of 180 carriers.)
- (2) Performance requirements. To support products represented in labeling as "disinfectants", killing on 59 out of each set of 60 carriers is required to provide effectiveness at the 95% confidence level.
- (b) General or broad-spectrum efficacy claims. Label claims of effectiveness as a "general disinfectant" or representations that the product is effective against a broad spectrum of microorganisms are acceptable if the product is effective against both Gram-positive and Gram-negative bacteria.
- (1) Test requirements. Use the AOAC Use-Dilution Method or the AOAC Germicidal Spray Product Test as in (a)(1). Sixty carriers must be tested against each of both *S. choleraesuis* and *S. aureus* with each of 3 samples, representing 3 different batches, one of which is at least 60 days old. (120 carriers per sample; a total of 360 carriers.)
- (2) Performance requirements. Same as in (a)(2) above.
- (c) Hospital or medical environment efficacy claims. Label claims for use of disinfectants in Hospital or medical environments are acceptable only for those products that are effective for general or broad-spectrum disinfection and additionally against the nosocomial bacterial pathogen Pseudomonas aeruginosa.
- (1) Test requirements. Employ the AOAC Use-Dilution Method or the AOAC



Germicidal Spray Products Test as in (a)(1). Sixty carriers must be tested against each of *S. choleraesuis*, *S. aureus*, and *Pseudomonas aeruginosa* ATCC 15442 with each of 3 samples, representing, one of which is at least 60 days old. (180 carriers per sample; a total of 540 carriers.)

- (2) Performance requirements. Same as in (A)(2) above.
- (d) Other microorganisms. Substantiated label claims of effectiveness of a disinfectant against specific microorganisms other than the designated test microorganism(s) are permitted, but not required, provided that the target pest is likely to be present in or on the recommended use areas and surfaces and thus may present a potential problem.
- (1) Test requirements. Effectiveness of disinfectants against specific microorganisms other than those named in the AOAC Use Dilution Method, AOAC Germicidal Spray Products Test, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method (II. Confirmative In-Vitro Test), but not including viruses, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products Test as in (a)(1). Ten carriers must be tested against each specific microorganism with each of 2 samples, representing 2 different batches. (10 carriers per sample, a total of 20 carriers.)
  - (2) Performance requirements. Killing of the test microorganism on all carriers is required. Plate count data, on appropriate culture media, must be submitted on each test microorganism to disclose that a concentration of at least  $10^4$  microorganisms survive the carrier-drying step in order to provide meaningful results.



## EFFICACY DATA REQUIREMENTS

### Supplemental Recommendations

When an antimicrobial Agent is intended for a use pattern that is not reflected by the test conditions specified in the Recommended Methods, one or more test conditions specified in the method must be modified and/or supplementary data developed in order to provide meaningful results relative to the conditions of use. The following basic information is critical to the development and submission of appropriate data.

#### 1. EXPOSURE PERIOD

All products tested by the recommended methods may be tested at the exposure periods prescribed in those methods. However, if the product is intended for use at exposure periods shorter or longer than those specified in the method, the method must be modified, in a manner acceptable to the Agency, to reflect the deviation in exposure intended. A modification to provide a shorter exposure period is restricted by the manipulative limitations inherent in the method, while a modification to provide a longer exposure period is restricted by the conditions applicable to the use pattern. If a ten-minute exposure period is necessary for the antimicrobial agent to be effective against the test microorganism the product cannot be represented as an "instantly active" product, or cannot be represented as being "effective in 30 seconds, "one minute," or at any time period shorter than 10 minutes. Also, the product cannot be recommended for use in a manner which is inconsistent with the exposure period necessary for effectiveness (as, for example, "Spray on surface, and immediately wipe with clean cloth") unless the standard method has been modified and reflects efficacy under such conditions of use. In any case, the exposure period or manner of use necessary to provide efficacy must be featured prominently on the product label.

#### 2. TYPE OF SURFACE

When an antimicrobial agent is intended to be effective in treating a hard porous surface, some of the Recommended Methods may be modified to simulate this more stringent condition by substitution of a porous surface carrier (such as a porcelain penicylinder or unglazed ceramic tile) for the non-porous surface carrier (stainless steel cylinder or glass slide) specified in the method. In addition, control data, described below in Supplemental Recommendation No. 6, must be developed to assure the validity of the test results when this modification of the method is employed. In no case may a surface carrier which represents a less stringent condition be substituted for a surface carrier which is specified in the Recommended Method.



### 3. HARD WATER

The Recommended Methods may be modified to demonstrate the effectiveness of an antimicrobial agent in hard water. The hard water tolerance level may differ with level of antimicrobial activity claimed. To establish disinfectant efficacy in hard water, all microorganisms (bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level.

### 4. ORGANIC SOIL

An antimicrobial agent identified as a "one-step" cleaner-disinfectant, cleaner-sanitizer, or one intended to be effective in the presence of organic soil must be tested for efficacy by the appropriate method(s) which have been modified to include a representative organic soil such as 5% blood serum. A suggested procedure to simulate in-use conditions where the antimicrobial agent is intended to treat dry inanimate surfaces with an organic soil load involves contamination of the appropriate carrier surface with each test microorganism culture containing 5% v/v blood serum (e.g., 19 ml test microorganism culture + 1 ml blood serum) prior to the specified carrier-drying step in the method. Control data, described below in Supplemental Recommendation No. 6, must also be developed to assure the validity of the test results when this modification is incorporated into the method. The organic soil level suggested is considered appropriate for simulating lightly or moderately soiled surface conditions. When the surface to be treated has heavy soil deposits, a cleaning step must be recommended prior to application of the antimicrobial agent. The effectiveness of antimicrobial agents must be demonstrated in the presence of a specific organic soil at an appropriate concentration level when specifically claimed and/or indicated by the pattern of use. A suggested procedure for incorporating organic soil load where the antimicrobial agent is not tested against a dry inanimate surface, such as the AOAC Fungicidal Test involves adding 5% v/v blood serum directly to the test solution (e.g., 4.75 ml test solution + 0.25 ml blood serum) before adding 0.5 ml of the required level ( $5 \times 10^6$  /ml) of conidia.

### 5. RE-USE

The Recommended Methods are designed to demonstrate efficacy of a freshly prepared antimicrobial solution intended for a single application. When the same use solution is intended for repeated applications, testing must be conducted in accordance with a test protocol specially designed to demonstrate retention of the claimed level(s) of antimicrobial activity in the use solution after repeated microbial and other appropriate challenges (such as supplemental recommendations indicated above) and stress conditions (such as an inadvertent or incidental dilution inherent in the use pattern) over the period of time or number of times specified in the directions for use.



## 6. MICROORGANISM SURVIVAL AFTER DRYING ON A HARD SURFACE

Quantitative determinations of the viable microbial concentration on the untreated control carrier after drying are required in order to determine the validity of the test results obtained with treated carriers when the Recommended Methods are modified to include such elements as (i) test microorganisms not specified in the method, (ii) substitution of a porous surface (e.g., porcelain penicylinder, unglazed ceramic tile) for the specified nonporous surface (stainless steel cylinder, glass slide), and/or (iii) an organic soil load. The detailed protocol for this testing must include: (i) preparation of inoculum, (ii) application of inoculum to the carrier, (iii) the time/temperature and relative humidity conditions for drying the microorganisms on the carrier, (iv) the technique for removal of the microorganisms from the carrier, and (v) the specific assay procedure indicating such details as replication, subculture media/diluents, and the incubation time/temperature conditions for the enumeration procedure employed. The test results must include the individual counts obtained by the method.

## 7. NEUTRALIZATION

For each antimicrobial product, procedures must be employed that will preclude residual effects of the active ingredient(s) in the subculture medium. A specific medium capable of neutralizing the antimicrobial effects of a product (whenever one is known) should be employed prior to the microbiological assay. Some of the Recommended Methods rely solely upon the selection of an appropriate subculture medium to neutralize the antimicrobial effects of certain general types of chemical compounds (active ingredients). However, to document absence of residual effects of the active ingredient(s) in the subculture medium, the following testing is necessary: (i) secondary subcultures must be performed to demonstrate that antimicrobial effects were overcome, or (ii) at the conclusion of the incubation period specified or employed in the method, the primary culture medium with test carrier must be inoculated with approximately 10 microorganisms/ml of the specific culture under test (documented by actual plate counts) and reincubated for the specified period to demonstrate that the subculture medium was capable of supporting bacterial growth.

## 8. BATCH REPLICATION FOR MODIFIED TESTS

Where the required batch replication has already been performed and accepted for a product registration with unmodified tests by the Recommended Methods, additional testing at the same use concentration under modified conditions (e.g., different exposure period, presence of organic soil or hard water, porous surface carrier, etc.) may be conducted with reduced batch replication, as follows: (i) for basic efficacy claims (e.g., sterilizers, disinfectants, or sanitizers), 2 samples, representing 2 different batches, instead of 3, and (ii) for supplemental efficacy claims (e.g., fungicides, virucides, or tuberculocides), one sample instead of 2.



## EFFICACY DATA REQUIREMENTS

### Reporting of Data

Systematic and complete descriptions of the tests employed and the results obtained are essential for proper review and evaluation of product performance by the Agency. All test reports must include identification of the testing laboratory or organization, when and where the tests were conducted, and the name of the person(s) responsible for the conduct of the tests.

- (1) Recommended Methods. When the Recommended Methods (such as standard AOAC tests) are employed to develop efficacy data, certain minimal information must be provided in the test report. The report must include, but is not limited to, the following:
  - (a) Test employed, and any modifications thereto;
  - (b) Test microorganisms employed, including identification of the specific strain (ATCC or other);
  - (c) Concentration or dilution of product tested and how prepared;
  - (d) Number of samples, batches, and replicates tested;
  - (e) Preparation date of each product batch (individually formulated preparation of the product);
  - (f) Phenol resistance of test microorganisms (actual test results);
  - (g) Identification of all material or procedural options employed, where such choice is permitted or recommended in the test method selected (for example, growth media, drying time for inoculated carriers, neutralizer and/or subculture media, secondary subculturing);
  - (h) Complete report of results obtained for each individual replication;
  - (i) Any control data essential to establish the validity of the test.
- (2) Modification of Recommended Methods. Where Recommended Methods are significantly modified to support specific claims and/or use patterns for a product, the protocol employed for modifying the test must be provided in specific detail with the test report. The applicant may submit the proposed modification for review and evaluation prior to initiation of the test.
- (3) Other Methods. When Recommended Methods, or modification thereto, are not employed to develop efficacy data (such as actual in-use or many kinds of

simulated-use testing), complete testing protocols must be submitted with the test reports. All materials and procedures employed in testing must be described in a manner consistent with original research reports published in technical or scientific journals. Where references to published reports or papers are made, copies or reprints of such references should be provided with the test reports. Proposed testing protocols for in-use or simulated-use studies of this kind may be submitted for review and evaluation by the Agency prior to initiation of the tests.



**EFFICACY DATA REQUIREMENTS:**

**VIRUCIDES**

(Proposed method prepared by Registration Division, Office of Pesticide Programs, EPA, 1976)

The Agency will accept adequate data developed by any virological technique which is recognized as technically sound, and which simulates to the extent possible in the laboratory the conditions under which the product is intended for use. For virucides whose use-directions identify the product as one intended for use upon dry, inanimate, environmental surfaces (such as floors, tables, cleaned and dried medical instruments, etc.), carrier methods, which are modifications of either the AOAC Use-Dilution Method (for liquid surface disinfectants) or the AOAC Germicidal Spray Products Test (for surface spray disinfectants), must be used in the development of the virological data. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of two different batches of disinfectant must be tested against a recoverable virus titer of at least  $10^4$  from the test surface (petri dish, glass slide, steel cylinder, etc.) for a specified exposure period at room temperature. The virus is then assayed by an appropriate virological technique. The protocol for the viral assay must provide the following information:

- (i) The virus recovery from a minimum of 4 determinations per each dilution in the assay system (tissue culture, embryonated egg, animal infection, or whatever assay system is employed).
- (ii) Cytotoxicity controls: The effect of the germicide on the assay system from a minimum of 4 determinations per each dilution.
- (iii) The activity of the germicide against the test virus from a minimum of 4 determinations per each dilution in the assay system.
- (iv) Any special methods which were used to increase the virus titer and to detoxify the residual germicide.
- (v) The ID-50 values calculated for each assay.
- (vi) The test results shall be reported as the reduction of the virus titer by the

activity of the germicide (ID-50 of the virus control less the ID-50 of the test system), expressed as  $\log_{10}$  and calculated by a statistical method (Reed and Muench, 1938; Litchfield and Wilcoxon, 1949; as examples).

- (vii) For virucidal data to be acceptable, the product must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident (as in attached tables) at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. The calculated viral titers must be reported with the test results.

A typical laboratory report of a single test with one virus (recovered from a treated surface) involving a tissue culture, therefore, would include the details of the methods employed and the information in the attached tables.

Claims of virucidal activity for a product must be restricted to those viruses which have actually been tested. Separate studies on two batches of product are required for each virus.

#### References

Litchfield, J. T., Jr., and F. Wilcoxon. 1949. A simplified method of evaluating dose-effect experiments. Jour. Pharma. Exp. Therapy, 96: 99-113.

Reed, L. J., and H. Muench. 1938. A simple method of estimating 50 per cent end-points. Amer. Jour. Hygiene, 27: 493-497.



Table 1 - Test Results

Dilution of Virus	Virus - Disinfectant <sup>1</sup>	Virus - Control <sup>1</sup>	Cytotoxic- Control
10 <sup>-1</sup>	T T T T		+ + + + T T T T
10 <sup>-2</sup>	T T T T		+ + + + T T T T
10 <sup>-3</sup>	T O O O		+ + + + T O O O
10 <sup>-4</sup>	O O O O		+ + + + O O O O
10 <sup>-5</sup>	O O O O		+ + + + O O O O
10 <sup>-6</sup>	O O O O		+ + + O O O O O
10 <sup>-7</sup>	O O O O		+ O O O O O O O
10 <sup>-8</sup>	O O O O		O O O O O O O O

1 Recovery of virus from surfaces demonstrated by cytopathogenic effect, fluorescent antibody, plaque count, animal<sup>1</sup> response, or other recognized acceptable technique.

Note: T = toxic; + = virus recovered; O = no virus recovered.

Table II-Calculation of the Tissue Culture Infective Dose 50 (TCID<sub>50</sub>)

Virus dilution inoculated	No. infected/ No. inoculated	No. infected	No. not infected	Accumulated Values			per cent infected
				No. infected	No. not infected	No. infected/ No. inoculated	
10 <sup>-1</sup>	4/4	4	0	24	0	24/24	100
10 <sup>-2</sup>	4/4	4	0	20	0	20/20	100
10 <sup>-3</sup>	4/4	4	0	16	0	16/16	100
10 <sup>-4</sup>	4/4	4	0	12	0	12/12	100
10 <sup>-5</sup>	4/4	4	0	8	0	8/8	100
10 <sup>-6</sup>	3/4	3	1	4	1	4/5	80
10 <sup>-7</sup>	1/4	1	3	1	4	1/5	20
10 <sup>-8</sup>	0/4	0	4	0	8	0/8	0

$$\text{TCID}_{50} = 10^{6.5}$$



Table III-Calculations of the Tissue Culture Lethal Dose 50 (TCLD<sub>50</sub>)

Virus dilution inoculated	No. toxic/ No. inoculated	No. toxic	No. not toxic	Accumulated Values			
				No. toxic	No. not toxic	No. toxic/ No. inoculated	percent toxic
10 <sup>-1</sup>	4/4	4	0	9	0	9/9	100
10 <sup>-2</sup>	4/4	4	0	5	0	5/5	100
10 <sup>-3</sup>	1/4	1	3	1	3	1/4	25
10 <sup>-4</sup>	0/4	0	4	0	7	0/7	0
10 <sup>-5</sup>	0/4	0	4	0	11	0/11	0
10 <sup>-6</sup>	0/4	0	4	0	15	0/15	0
10 <sup>-7</sup>	0/4	0	4	0	19	0/19	0
10 <sup>-8</sup>	0/4	0	4	0	23	0/23	0

$$\text{TCID}_{50} = 10^{2.7}$$

Therefore: Virus inactivation =  $\text{TCID}_{50} - \text{TCLD}_{50} = 10^{3.8} \log 10$   
 Claims for virucidal activity for a product must be restricted to those  
 viruses which have actually been tested.

EFFICACY DATA REQUIREMENTS

Sterilizers

A "sterilizer" is an antimicrobial pesticide that destroys or eliminates all forms of microbial life in the inanimate environment, including bacterial spores. The term "sporicide" is deemed to be synonymous with "sterilizer". Since sterilization includes eradication of all living microorganisms, such claims are intrinsically related to protection of human health. The following apply to all products represented in labeling as sterilizing or sporicidal agents.

- (1) Test requirements. The AOAC Sporicidal Test is required for substantiating sterilizing claims. Sixty carriers-representing each of two types of surfaces (porcelain penicylinders and silk suture loops) are required to be tested against spores of both Bacillus subtilis ATCC 19659 and Clostridium sporogenes ATCC 3584 on three product samples representing three different batches, one of which is at least 60 days old (240 carriers per sample; a total of 720 carriers). Any sterilizing agent (liquid, vapor, or gas) which is recommended for use in a specific device must be tested by the AOAC Sporicidal Test in that specific device and according to the directions for use.
- (2) Performance requirements. Killing on all of the 720 carriers is required. No failures are permitted. Data to support sterilizing claims must be confirmed by tests conducted by the Agency's Microbiology Laboratory before the data submitted for registration will be considered acceptable.

\*Note: Due to curtailment of laboratory operations at the EPA microbiology laboratory at Beltsville, MD, the required confirmatory validation data for a product as a sterilizer should be conducted by a second, independent laboratory of your choice (other than the laboratory which developed the original data). The following minimal confirmatory data must be developed on one sample of the product: Thirty carriers with each of the two types of surfaces (silk suture loops and porcelain penicylinders) against spores-of both Bacillus subtilis and Clostridium sporogenes (a total of 120 carriers) by the AOAC Sporicidal Test.



# VIRKON® S

## BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial, Animal, Veterinary, Agricultural and Horticultural Facilities.

### EFFECTIVE AGAINST:

#### BACTERIA

Actinobacillus pleuropneumoniae, Bacillus cereus, Bacillus subtilis, Bordetella avium (Alcaligenes faecalis), Bordetella bronchiseptica, Brucella abortus, Campylobacter jejuni, Campylobacter pyloridis, Chlamydia psittaci, Clostridium perfringens, Dermatophilus congolensis, Erysipelothrix rhusiopathiae, Eschericia coli, Haemophilus somnus, Klebsiella pneumoniae, Listeria monocytogenes, Moraxella bovis, Mycoplasma gallisepticum, Pasteurella hemolytica, Pasteurella multocida, Pseudomonas aeruginosa, Salmonella choleraesuis, Salmonella enteritidis, Salmonella typhimurium, Serpulina (Treponema) hyodysenteriae, Shigella sonnei, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus equi, Streptococcus pyogenes, Streptococcus suis, Taylorella equigenitalium

#### FUNGI

Aspergillus fumigatus, Candida albicans, Fusarium moniliforme, Trichophyton mentagrophytes

#### VIRUSES

Avian infectious bronchitis virus, Avian influenza virus, Avian laryngotracheitis virus, Bovine adenovirus Type 4, Bovine Papilloma virus, Bovine viral diarrhea (BVD) Pestivirus, Calf rotavirus, Canine parvovirus, Duck adenovirus, Equine arteritis virus, Equine herpes virus Type 1, Equine herpes virus Type 3, Equine influenza virus Type A, Feline calicivirus, Feline infectious peritonitis (FIP) virus, Feline panleukopenia virus, Feline rhinotracheitis virus, Human Immunodeficiency Virus (HIV-I), Infectious bovine rhinotracheitis virus, Infectious bronchitis virus, Infectious bursal disease (Gumboro) virus, Infectious canine hepatitis adenovirus, Newcastle disease virus, Parainfluenza virus, Parvovirus, PRRS virus, Pseudorabies virus, Simian virus 40 (SV40), TGE-Coronavirus, Turkey herpes virus

#### ACTIVE INGREDIENTS

Potassium peroxymonosulfate .....	20.4%
Sodium Chloride .....	1.5%
INERT INGREDIENTS .....	78.1%
TOTAL .....	100.0%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN  
DANGER

See Back Panel for Additional Precautions

EPA Reg. No. 62432-1

10 lbs Net Weight

EPA Est. No. 62432-EN-001

VIRKON S is a registered trademark of and manufactured by Antec International Limited

Windham Road, Chilton Industrial Estates

Sudbury, Suffolk CO10 6XD, England

Tel: (01787) 377305 Telex: (01787) 987495 Fax: (01787) 310846

U.S. Patent No. 4822512

Total proven antimicrobial with broad spectrum activity and fast acting formulation for cleaning and disinfection in a single operation.

#### **DIRECTIONS FOR USE**

Federal law prohibits use of the product in a manner inconsistent with its labeling.

VIRKON S at 1% (1:100) solution is generally suitable for cleaning and disinfecting. This powder formula is easily diluted for use in manual or machine operations.

#### **POULTRY PRODUCTION/RATITE PRODUCTION**

VIRKON S is recommended for use in hatcheries, in chicken houses, in Ratite production and processing plants.

**HATCHERIES:** VIRKON S at 1% (1:100) solution is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays and plastic chick boxes (use 2% solution for Mycoplasma and 3% solution for Aspergillus fumigatus). After contact for ten minutes rinse with potable water.

#### **BROILER/BREEDER HOUSES:**

Remove manure and litter and spray floors, ceilings and side walls with VIRKON S at 1% (1:100). Thoroughly wash waterers and feeders with a 1% (1:100) solution of VIRKON S (use 2% solution for Mycoplasma and 3% solution for Aspergillus fumigatus). After contact for ten minutes rinse with potable water.

**AIR SANITIZING:** Use VIRKON S at 1% (1:100) solution. Fog the atmosphere until surfaces are moist.

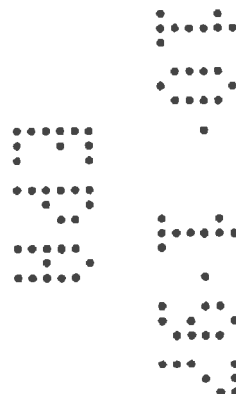
VIRKON S is recommended for use in fogging (wet misting) operations for aerial disinfection as an adjunct either preceding or following regular cleaning and disinfecting procedures in the presence of poultry.

**SITE SECURITY:** To avoid introduction of infection onto a farm or transfer of infection from house to house, use Virkon S at 1% (1:100) for foot baths, wheel dips and vehicle sprays.

VIRKON S at 1% (1:100) is suitable. Fog (wet mist) until the area is moist using automatic wet foggers according to manufacturer's use directions.

**PROCESSING PLANTS:** For disinfecting and cleaning walls, ceilings, and floors, spray at a dilution of 1% (1:100).

VIRKON S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.





Total proven antimicrobial with broad spectrum activity and fast acting formulation for cleaning and disinfection in a single operation.

#### **DIRECTIONS FOR USE**

Federal law prohibits use of the product in a manner inconsistent with its labeling.

**VIRKON** at 1% (1:100) solution is generally suitable for cleaning and disinfecting (use 2% solution for *Mycoplasma* and 3% solution for *Aspergillus fumigatus*). After contact for ten minutes rinse with potable water.

#### **PORCINE PRODUCTION**

For application in Porcine facilities for cleansing and disinfection for barns, farrowing and nursing pens (sow and udder washing in presence of piglets), pig hatcheries, weaning accommodations, grower accommodations, finisher accommodations and materials and equipment required and associated with maintaining Porcine health program.

**AIR SANITIZING:** Use **VIRKON S** at 1% (1:100) solution. Fog the atmosphere until surfaces are moist.

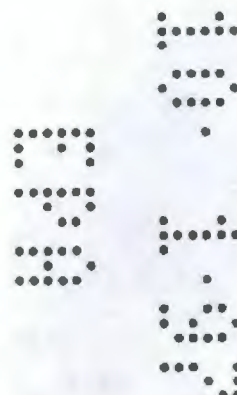
**VIRKON S** is recommended for use in fogging (wet misting) operations for aerial disinfection as an adjunct either preceding or following regular cleaning and disinfecting procedures in the presence of animals.

**SITE SECURITY:** To avoid introduction onto a farm or transfer of infection from house to house, use **Virkon S** at 1% (1:100) for foot baths, wheel dips and vehicle sprays.

**VIRKON S** at 1% (1:100) is suitable. Fog (wet mist) until the area is moist using automatic wet foggers according to manufacturer's use directions.

**PROCESSING PLANTS:** For disinfecting and cleaning walls, ceilings and floors spray at dilution of 1%.

**VIRKON S** passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.



Total proven antimicrobial with broad spectrum activity and fast acting formulation for cleaning and disinfection in a single operation.

#### **DIRECTIONS FOR USE**

Federal law prohibits use of the product in a manner inconsistent with labeling.

**VIRKON S** at 1% (1:100) solution is generally suitable for cleaning and disinfecting.

Add the contents of one packet (1.3 ounces) to one gallon of warm water. Solutions are stable for 7 days. Ten (10) minutes is maximum necessary contact time. One (1) gallon of solution is sufficient to treat 135 sq. ft.

#### **EQUINE APPLICATION**

**VIRKON S** is recommended for use in transportation of equine to and from race tracks, show rings and other equine events involving the exposure to large populations of horses, potentially harboring contagious or infectious disease entities. **VIRKON S** is for cleaning and disinfection of all surfaces, equipment, utensils, instruments and stables at 1% (1:100).

**For Topical Use on Animal:** Shampoo infected area with **VIRKON S** using a clean sponge. Rinse with clean water. Apply three times a day then repeat as necessary. **Stables, Horse Boxes, Tack Equipment and Feed Rooms:** Thoroughly dry clean. Then wash the area manually or with pressure washer with a 1% (1:100) **VIRKON S**. Rinse with clean water. **Blankets and rugs:** Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue. **Aerial spraying to control airborne diseases.** By using a knapsack sprayer with fine setting or a **VIRKON S SPRAY APPLICATION SYSTEM** which automatically sprays the area. Spray for 2-3 minutes twice daily, first thing in the morning and last thing at night.

**SHAMPOO:** Regular shampooing with **VIRKON** (1:100) will clean and protect your horse or pony. **VIRKON** produces a good lather and may be used as with any shampoo.

**TACK CLEANING:** Using a sponge wash until visibly clean. Rinse in clean water. Sponge with regular tack cleaning soap.

**INITIAL STABLE DISINFECTION:** Dry clean, ie, remove bedding and brush out. Thoroughly wet clean all surfaces manually or with a pressure washer. Allow to dry. Re-introduce bedding.

**DAILY STABLE DISINFECTION:** Spray stable twice daily with or without the horse present for a perfect disease free environment.

**BLANKETS, RUGS, BANDAGE WASHING:** Use as with any washing powder in a domestic washing machine or shampoo by hand. Rinse and allow to dry.

**AIR SANTITIZING:** Use **VIRKON** at 1% (1:100) solution. Fog the atmosphere until surfaces are moist.

**VIRKON S** is recommended for use in fogging (wet misting) operations for aerial disinfection adjunct either preceding or following regular cleaning and disinfecting procedures in the presence of animal.

**SITE SECURITY:** To avoid introduction of infection onto a farm or transfer from house to house, use **Virkon S** at 1% (1:100) for foot baths, wheel dips and vehicle sprays.



**(EQUINE PRODUCTION CONTINUED)**

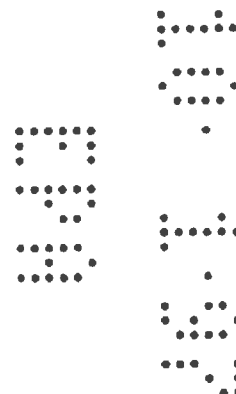
**VIRKON S** at 1% (1:100) is suitable. Fog (wet mist) until the area is moist using automatic wet foggers according to manufacturer's directions.

**VIRKON S** passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.

**AIR SANITIZING:** Use **VIRKON** at 1% (1:100) solution. Fog the atmosphere until surfaces are moist.

**VIRKON S** is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfection procedures in the presence of animals.

**VIRKON S** at 1% (1:100) is suitable. Fog (wet mist) until the area is moist using automatic wet foggers according to manufacturer's use directions.



Total proven antimicrobial with broad spectrum activity and fast acting formulation for cleaning and disinfection in a single operation.

#### **DIRECTIONS FOR USE**

Federal law prohibits use of the product in a manner inconsistent with its labeling.

**VIRKON S** at a 1% solution is generally suitable for cleaning and disinfecting.

#### **BOVINE PRODUCTION**

**VIRKON S** is recommended for barns, milking parlors, maternity and calving pens and associated equipment, quarantine, feedlot areas, loafing and holding pens, sheds, other areas and materials required for maintaining bovine health programs.

**AIR SANITIZING:** Use **VIRKON S** at 1% (1:100) solution. Fog the atmosphere until surfaces are moist.

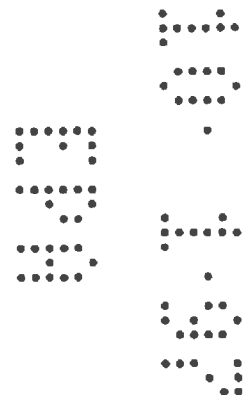
**VIRKON S** is recommended for use in fogging (wet misting) operations for aerial disinfection as an adjunct either preceding or following regular cleaning and disinfecting procedures in the presence of animals.

**SITE SECURITY:** To avoid introduction of infection onto a farm or transfer of infection from house to house, use **VIRKON S** at 1% (1:100) for foot baths, wheel dips and vehicle sprays.

**VIRKON S** at 1% (1:100) is suitable. Fog (wet mist) until the area is moist using automatic wet foggers according to manufacturer's use directions.

**PROCESSING PLANTS:** For disinfecting and cleaning walls, ceilings and floors spray at a dilution of 1% (1:100).

**VIRKON S** passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.





Total proven antimicrobial with broad spectrum activity and fast acting formulation for cleaning and disinfection in a single operation.

#### **DIRECTIONS FOR USE**

Federal law prohibits use of the product in a manner inconsistent with its labeling.

**VIRKON S** at 1% (1:100) solution is generally suitable for cleaning and disinfecting.

#### **COMPANION ANIMALS**

Add 1.3 ounces of **VIRKON S** to 1 gallon of warm water 1% (1:100). Solutions are stable for 7 days. Do not immerse soft metal objects in **Virkon S** for long periods (10 minutes maximum contact time).

**VIRKON S** is suitable for general use in veterinary practice facilities, particularly, where fecal, urinary or body fluid contamination occurs.

**SITE SECURITY:** To avoid introduction of infection onto premises or transfer of infection from house to house, use **Virkon S** at 1% (1:100) for foot baths, wheel dips and sprays.

**VIRKON S For Dog And Cat Shampoo:** Empty contents of one sachet into a bucket and fill with 1 gallon of water. Wash as with any shampoo and rinse with clean water.

**VIRKON S For Kennel Disinfection:** Thoroughly dry clean and remove bedding. Wet clean all surfaces with a sponge or with a trigger spray, allow to dry and re-introduce fresh bedding.

**VIRKON S For Blankets/Rug Wash:** Use **Virkon S** instead of your current washing powder to clean all rugs and blankets through your domestic washing machine.

**VIRKON S For Grooming Kit/Toy/Feed And Water Bowl Cleaner:** Using a sponge, wash utensils or toys until visibly clean. Rinse in clean water.

**VIRKON S For Daily Aerial Disinfection:** Regular spraying with **Virkon S** solution will remove dust and droplets from the atmosphere and destroy the infective organisms which they carry. Use your trigger spray (or back-pack for larger areas) and spray a fine mist onto the area for disinfection.

**VIRKON S is Recommended for Budgies, Pigeons and Canaries Cages, Aviaries, Lofts and Dove Shelters Disinfection:** Thoroughly dry clean and remove any bedding. Wet clean all surfaces manually or with a trigger spray, allow to dry and re-introduce fresh bedding.

**VIRKON S For Feeding and Water Utensils:** Using a sponge, wash any utensils until visibly clean and rinse in clean water.



## Budgies, Pigeons and Canaries Continued

**VIRKON S For Transportation For Racing Pigeons:** Diseases are transmitted very easily, especially during transportation. It is essential that vehicles are disinfected before pigeons are transported. Wet clean all surfaces with Virkon S solution using a Back-pack sprayer and allow to dry. This will create a disease free environment for the pigeons to travel.

**VIRKON S is recommended for Rabbits and Guinea Pigs Hutch and Cage Disinfection:** Thoroughly dry clean and remove bedding. Wet clean all surfaces manually or with a trigger spray, allow to dry and re-introduce fresh bedding.

**VIRKON S For Feed Bowl/Water Bottle Cleaner:** Using a sponge, wash bowls until visibly clean and rinse in clean water. Wash bottles thoroughly with Virkon S solution and rinse with clean water.

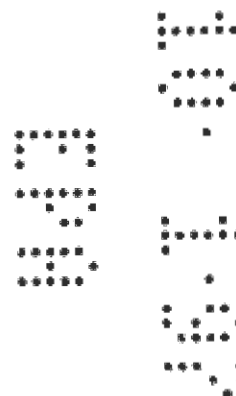
**VIRKON S Daily Aerial Disinfection:** Using a trigger spray bottle spray a fine mist of Virkon S solution on the area for disinfection. Regular spraying with Virkon S solution will remove dust and droplets from the atmosphere and destroy the infective organisms which they carry.

**VIRKON S is Recommended for Hamsters, Gerbils and Mice Cage Disinfection:** Thoroughly dry clean and remove bedding. Wet clean all surfaces manually or with a trigger spray, allow to dry and re-introduce fresh bedding.

**VIRKON S for Feed and Water Utensil Cleaning:** See rabbits and guinea pigs.

**VIRKON S for Daily Aerial Disinfection:** See rabbits and guinea pigs.

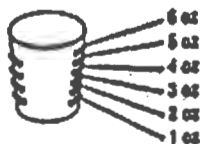
**VIRKON S is recommended for Reptiles and Insects Tank Disinfection:** Empty tank of any water or bedding and remove animal into alternative habitat. Mix Virkon S solution and using a sponge, wash all surfaces until visibly clean, rinse with clean water, allow to dry and re-introduce fresh water or bedding and animal.





## DILUTION CHART

Quantity of Final Solution	1% Solution	2% Solution
American		
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces



Brim full - contains  
7 ounces



This measure cap holds  
when filled level 17.5  
ounces.

For **DISINFECTING** use a rate of 7.5 gallons/1000 sq. ft.  
For **CLEANING AND DISINFECTING** use a rate of  
15 gallons/1000 sq. ft.

## PRECAUTIONARY STATEMENTS

### HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS

#### DANGER

Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive statement refers to powder only, not in use solution.

## PRACTICAL TREATMENT

**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention if irritation persists.

**IF INHALED** or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

**IF SWALLOWED:** Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

**NOTICE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

**STORAGE AND DISPOSAL:** Store in a cool dry place in tightly closed container. Keep out of reach of children. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

Manufactured by  
Antec International Limited  
Windham Road, Chilton Industrial Estates  
Sudbury, Suffolk CO10 6XD, England  
Tel: (01787) 377305 Telex: (01787) 987495 Fax: (0178) 310846  
EPA Reg. No. 62432-1-12281 EPA Est. No. 62432-1EN-001

## Company Data Report

Company No.: 62432

Name: ANTEC INTERNATIONAL LTD

Address: WINDHAM ROAD, CHILTON INDUSTRIAL ESTATE  
SUDBURY, SUFFOLK, 00000  
UK

Contact: FRANCIS AUCHINCLOSS

Phone: (813) 424-5505

Agent: Y

Consortium: N

Undeliverable: N

Company Types

-----  
EstablishmentActive  
Flag-----  
Y

Agent information

Name: FARNAM COMPANIES, INC.

Address: 301 WEST OSBORN  
PHOENIX, AZ 85013

Contact: DR. DOUGLAS H. ROSS

Phone: (602) 207-2108



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR - 4 1998

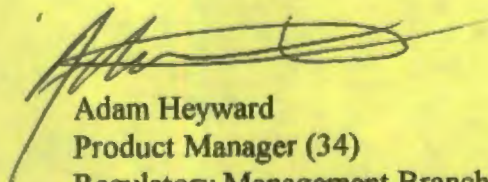
Jeff Jones, Agent  
Antec International LTD  
c/o Delta Analytical Corp.  
7910 Woodmont Avenue, Suite #1000  
Bethesda, MD 20814

Dear Mr. Jones:

Subject: Revised labeling  
Virkon S  
EPA Registration No. 62432-1  
Amendment application February 18, 1998

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records.

Sincerely yours,

  
Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510W)

Enclosure

cc: Dr. Alan R. Wagner		CONCURRENCES					
SYMBOL							
SURNAME							
DATE							



February 18, 1998

Mr. Adam Heyward, PM 34  
Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504CW)  
US EPA  
401 M Street SW  
Washington, DC 20460 0001

Re: Virkon S; EPA Reg. No. 62432-1; **Minor** Label Amendment to Conform with Agreement Dated February 9, 1998

Dear Adam:

Pursuant to our telephone conversation and agreement of February 9, 1998 (attached), I am submitting three copies of revised labeling for Virkon S. You will note the following changes from the November 17, 1997, draft label which we discussed on the telephone:

- ▲ On page 2, column 1, we have replaced the term "Clostridial diarrhea" with the species causing this disease, "Clostridia perfringens;" in the same listing we have corrected the spelling of "Gianders" to "Glanders."
- ▲ On page 2, column 1, under Equine Fungi, we have replaced Dermatophytosis (ringworm and Mud Fever) with the species causing these diseases, Trichophyton spp.(Ringworm) and Trichophyton spp.(Mud Fever).
- ▲ On page 2, column 2, under Viruses we have identified the virus causing Egg Drop Syndrome as Egg Drop Syndrome Adenovirus.
- ▲ On page 5, we have removed the use pattern calling for topical use on animals as this use has not been previously approved by USDA.



- ▲ In addition to the changes previously discussed we have also added the term, "Poultry," to the headings for bacteria, viruses and fungi on page 2, column 2 to clarify these are pathogenic organisms specific to poultry.

Since the November 17 label has already been reviewed by Ms. Wingfield, I am hopeful this label can be stamped within a few weeks. I am enclosing a fax-back Notice of Completeness Determination form as suggested in the proposed Antimicrobial Procedural Rule.

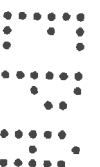
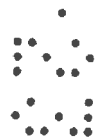
If you have questions or need additional information, please contact me.

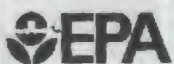
Sincerely,



T. Jeffrey Jones, Agent  
Antec International Ltd.

Enclosure





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number  
**245146**

### Application for Pesticide - Section I

1. Company/Product Number <b>62432-1</b>	2. EPA Product Manager <b>MR. ADAM HEYWARD</b>	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>VIRKON S / ANTEC INTERNATIONAL LTD<sup>1</sup></b>	PM# <b>34</b>	
5. Name and Address of Applicant (Include ZIP Code) <b>ANTEC INTERNATIONAL LTD<sup>1</sup> c/o DELTA ANALYTICAL CORP. 7910 WOODMONT AVENUE, SUITE # 1000 BETHESDA, MD 20814</b> <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

### Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

**MINOR LABEL AMENDMENT, PURSUANT TO FEBRUARY 9, 1998 AGREEMENT.**

### Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name <b>JEFF JONES</b>		Title <b>AGENT FOR ANTEC</b>		Telephone No. (Include Area Code) <b>(301) 652-5495</b>	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received  (Stamped) 
2. Signature 		3. Title <b>AGENT FOR ANTEC</b>			
4. Typed Name <b>JEFF JONES</b>		5. Date <b>2/18/98</b>			



## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

**Submission of Labeling** - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data** - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A** - Check the appropriate action for which you are submitting this form.

**SECTION I** - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II** - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III** (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

**SECTION IV** (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "re-reg," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



**VIRKON-S<sup>®</sup>**  
**BROAD SPECTRUM DISINFECTANT**

**For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities**

**ACTIVE INGREDIENTS:**

Potassium peroxymonosulfate.....	20.4%
Sodium Chloride.....	1.5%
INERT INGREDIENTS.....	<u>78.1%</u>
TOTAL.....	100.0%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

See Back [Side] Panel[s] for Additional Precautions

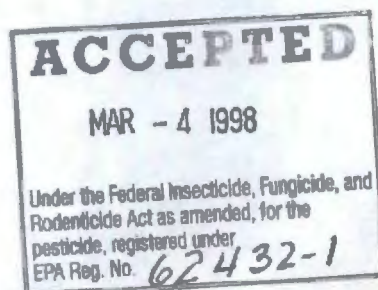
\_\_\_ lbs. (\_\_\_) Net Weight

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

**ANTEC INTERNATIONAL LTD.**  
Windham Road, Chilton Industrial Estates  
Sudbury Suffolk CO10 6XD, England  
Tel: (1787) 77305 Telex: 987495 Fax: (1787) 310846

**VIRKON S is a registered trademark of and manufactured by Antec International Limited**  
**US Patent No. 4822512**



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**EFFECTIVE AGAINST:**

**EQUINE BACTERIA**

Clostridium perfringens  
Fistulous withera (Poll Evil)  
Taylorella equigenitalis  
Streptococcus equi (Strangles)  
Pseudomonas mallei  
(Glanders)  
Bordetella bronchiseptica

**EQUINE VIRUSES**

African Horse Sickness  
African Viral Arteritis  
(Pink Eye)  
Coital Exanthema  
Myeloencephalopathy  
Rhinopneumonitis  
Equine Infectious Anemia  
(Swamp Fever)  
Equine papillomatosis  
Equine Contagious Abortion  
Adenovirus Pneumonia  
Equine Influenza (The Cough)

**EQUINE FUNGI**

Trichophyton spp. (Ringworm)  
Trichophyton spp.  
(Mud Fever)  
Fusarium moniliforme

**BOVINE BACTERIA**

Moraxella bovis  
Mycobacterium bovis  
Haemophilus somnus

**BOVINE VIRUSES**

Calf rotavirus  
Infective Bovine  
Rhinothracheitis  
Bovine Adenovirus Type 4  
Pseudorabies  
Foot & Mouth Disease ✓

**BOVINE FUNGI**

Fusarium moniliforme

**POULTRY BACTERIA**

Streptococcus pyogenes  
Campylobacter pyloridis  
Klebsiella pneumoniae  
Escherichia coli  
Salmonella typhimurium  
Salmonella choleraesuis  
Pseudomonas aeruginosa  
Staphylococcus aureus  
Staphylococcus epidermidis  
Mycoplasma gallisepticum  
Clostridium perfringens  
Bordetella avium

**POULTRY VIRUSES**

Newcastle Disease  
Infectious Bronchitis  
Infectious Bursal Disease  
Avian Laryngotracheitis  
Avian Influenza  
Marek's Disease  
Egg Drop Syndrome  
Adenovirus

Turkey Herpes Virus  
Duck Herpes Virus  
Duck Viral Enteritis

**POULTRY FUNGI**

Aspergillus flavus  
Aspergillus fumigatus  
Candida albicans

**SWINE BACTERIA**

Bordetella bronchiseptica  
Pasteurella multocida  
Actinobacillus  
pleuropneumonia  
Treponema hyodysenteria  
Clostridium perfringens

**SWINE VIRUSES**

Hog Cholera  
Swine Influenza  
Porcine parvovirus  
Rotaviral diarrhea  
Vesicular stomatitis  
Pseudorabies  
Porcine Reproductive and  
Respiratory Syndrome  
(PRRS)  
African Swine Fever  
Foot and Mouth Disease

**SWINE FUNGI**

Fusarium moniliforme

**COMPANION ANIMALS**

**BACTERIA**

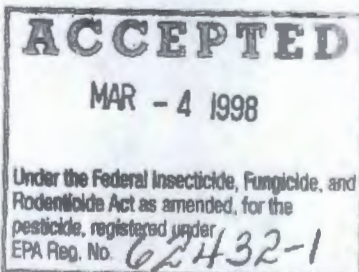
Streptococcus aureus  
Streptococcus pyogenes  
Klebsiella pneumoniae  
Pseudomonas aeruginosa

**VIRUSES**

Canine Parvovirus  
Distemper  
Leptospira canicola  
Feline parvovirus  
Feline herpes  
Feline calicivirus

**FUNGI**

Microsporum canis



13 February 1998



**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
DANGER**

Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive statement refers to powder only not in use solution.

**FIRST AID**

**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention if irritation persists.

**IF INHALED:** If symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

**IF SWALLOWED:** Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

**NOTICE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

**BROAD SPECTRUM DISINFECTANT**

**VIRKON-S** is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material. ***VIRKON-S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.***

**DIRECTIONS FOR USE**

Federal law prohibits use of this product in a manner inconsistent with its labeling

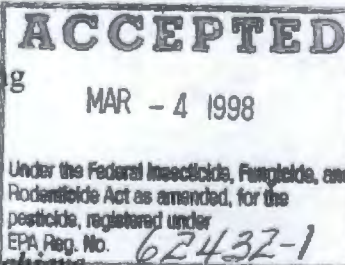
This powder formula is easily diluted for use in manual or machine operations.

***VIRKON-S DILUTION CHART***

*Fill container with desired amount of water and add VIRKON-S powder to achieve recommended solution concentration.*

<i>Quantity of Water</i>	<i>Amount of Powder for 1% Solution</i>	<i>Amount of Powder for 2% Solution</i>
<i>1 Quart</i>	<i>0.3 ounces</i>	<i>0.7 ounces</i>
<i>1 Gallon</i>	<i>1.3 ounces</i>	<i>2.7 ounces</i>
<i>10 Gallons</i>	<i>13.4 ounces</i>	<i>26.7 ounces</i>
<i>50 Gallons</i>	<i>66.8 ounces</i>	<i>133.5 ounces</i>

*1.3 oz. measuring scoop is provided.*





**Add [1.3 oz. (1 scoop) of VIRKON-S] [the contents of one VIRKON-S packet] to one gallon of warm water. Solutions are stable for 7 days. Do not soak metal objects for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.**

#### POULTRY [AND RATITE PRODUCTION]

**CONTROLS:** Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*. Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium* and *Mycoplasma gallisepticum*.

**HATCHERIES:** VIRKON-S at 1% solution *can be used* for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). VIRKON-S at 1-2% solution is recommended for use in fogging (wet misting) operations as a *supplemental measure*, either *before or after* regular cleaning and *disinfecting* procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

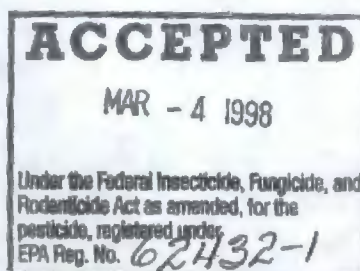
**BROILER/BREEDER HOUSES:** *Remove chickens [birds], feed, and water troughs, then remove manure and litter. Spray floors and walls with VIRKON-S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of VIRKON-S (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus). After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.*

**FOR AIR SANITIZING:** Use VIRKON-S at 1-2% solution, *and fog until* surfaces are moist. Allow at least 2 hours before entering *treated area*. *Rinse foggers and sprayers with water following use.*

**PROCESSING PLANTS:** *Spray VIRKON-S at 1% solution to disinfect and clean walls, ceilings and floors.*

#### SWINE [PRODUCTION]

**CONTROLS:** Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine Fever and Foot and Mouth Disease. Bacteria of Pleuropneumonia, *Treponema hyodysenteriae*, and *Clostridium perfringens*. Fungi: *Fusarium moniliforme*.



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**VIRKON-S at 1% solution** is recommended for *cleaning and disinfecting* farrowing units, nurseries, finisher houses and processing plants (use a 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*.)

**VIRKON-S at 1-2% solution** is recommended for use in fogging (wet misting) operations or as a *supplemental measure* either *before* or *after* regular cleaning and *disinfecting* procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. *Rinse foggers and sprayers with water following use.*

### EQUINE [PRODUCTION]

#### BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

##### CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis. Bacterial: Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders). Fungi: Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), and Fusarium moniliforme.

**APPLICATIONS:** For cleaning and *disinfecting* all surfaces, equipment, utensils and instruments in Veterinary practices [, kennels, stables, catteries, etc].

##### USES:

~~Topical Use On Animal: Shampoo infected area with a 1% solution of VIRKON-S using a clean sponge. Rinse with clean water. Apply three times a day. Repeat as necessary.~~

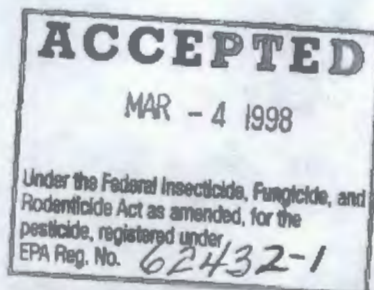
Stables, [Horse Boxes, ][Box ]Stalls, Tack ,[Equipment,] and Feed Rooms: Thoroughly *clean and dry* [dry clean] *surfaces*, then wash the area manually or with pressure washer with a 1% VIRKON-S solution. Rinse with clean water.

Blankets, [Saddle Pads] [and] Rugs: Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

Aerial Spraying to control airborne diseases: *Use a hand [or knapsack] sprayer with fine setting*, or an *automatic* spraying system. Spray a 1% *VIRKON-S solution* for 2-3 minutes twice daily [, first thing in the morning and last thing at night]. *Rinse sprayers with water after use.*

### BOVINE [PRODUCTION]

**CONTROLS:** Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies; Bacteria of Maraxella bovis, Haemophilus somnus and Mycobacterium bovis; Fungi of Fusarium moniliforme.



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A 1% solution of VIRKON-S is recommended to *clean and disinfect* areas associated with bovine *housing* [stabling], hospital [quarantine] pens and feedlot facilities.

#### COMPANION ANIMALS

CONTROLS: Viruses Canine Parvovirus, Distemper, *Leptospira canicola*, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of *Staphylococcus aureus*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*; Fungi of *Microsporum canis*.

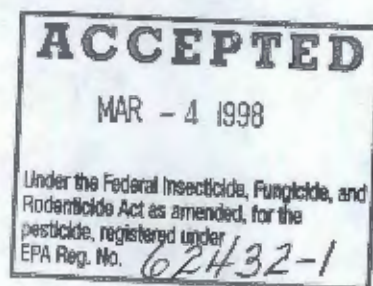
[APPLICATIONS:] A 1% solution of VIRKON-S is recommended as a "one step" cleaning and *disinfecting* procedure for all surfaces, equipment, instruments, utensils and *cages* [caging systems] within [associated with] [Veterinary Medical Hospitals,] [infectious disease wards,] [quarantine areas,] [Humane Society facilities,] [laboratory animal quarters,] grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in VIRKON-S for long periods - 10 minutes is maximum contact time.

#### STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

DISPOSAL: Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals



13 February, 1998

## Notice of Completeness Determination

Applicant                      Antec International Ltd.

Product Name                Virkon S

EPA Reg. No.                62432-1

Application Dated          February 18, 1997

Date of EPA Receipt        \_\_\_\_\_

Expected Decision Date    \_\_\_\_\_

EPA has made a preliminary determination that the application referenced above is complete.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name

**Please fax to:      Jeff Jones, Agent  
                         Antec International Ltd.  
                         301 652 5408**

12

25

25

360





**Facsimile Message**

Total No. of Pages Including Cover: 1

**February 12, 1998**

**To: Connie Welch**  
**From: Jeff Jones**  
**Subj: Completion of Antec-Farnam Action**

I received the signed version of our agreement resolving the Antec-Farnam matter this morning. You've made members of our team in eastern England, Phoenix, AZ, and here in Bethesda very happy today. Thanks to you and your colleagues, Michele Wingfield and Adam Heyward, for your kind assistance in concluding this matter expeditiously in a manner that serves both the government's and the registrant's best interests.

Best regards,

cc: Rick Auchincloss, Antec International Ltd.  
Doug Ross, Farnam Companies, Inc.

7910 Woodmont Avenue Suite 1000 Bethesda, Maryland 20814  
(301) 652-5495 FAX (301) 652-5408

TOTAL P.01

**Facsimile Message**

Total No. of Pages Including Cover: 6

February 9, 1998

To: Connie Welch  
Michele Wingfield  
Adam Heyward

From: Jeff Jones

Subj: Resolution of Antec-Farnam Matter; EPA Reg. No. 62432-1

Following up on our telephone conversation this afternoon I am attaching a letter previously submitted to the Agency appointing me a "co-agent" with Dr. Wagner for Antec matters.

I also attach an Agent letter covering Farnam Companies, Inc. activities on Virkon S. Contrary to what I said in our telephone conversation, Farnam will be handling Virkon S under a distributor label. Accordingly I am also attaching EPA Form 8570-5 covering this distributor relationship.

Based on our discussions this afternoon you have asked for the following clarifications/changes on the November 17, 1997, version of the label:

- On page 2, column 1, under heading Equine Bacteria you have asked that we add the species causing Clostridial diarrhea; in the same listing correct the spelling of "Gianders" to "Glanders."
- On page 2, column 1, under Equine Fungi, you have asked that we list the fungi causing Dermatophytosis, both ringworm and Mud Fever.
- On page 2, column 2, under Viruses you have asked us to identify the virus causing Egg Drop Syndrome or list the entry as Egg Drop Syndrome Virus if that is appropriate.

7910 Woodmont Avenue Suite 1000 Bethesda, Maryland 20814  
(301) 652-5495 FAX (301) 652-5408



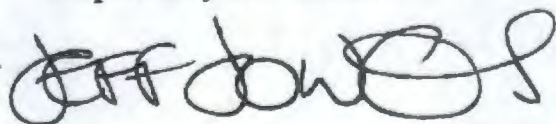
- On page 5, under Equine Production, you have requested documentation of USDA authorization for topical use of Virkon S on animals.
- I also understand that you will be supplying us with copies of general guidance regarding labeling of animal health products to assist us in improving advisory language on our label.

During our conversation, I have agreed on behalf of Antec to make these clarifications and changes at the next label printing. I will supply you with the text of the revised label within a week. You have agreed to permit us to begin shipping product immediately using our existing stock of bags printed with the November 17, 1997, label text recognizing that the clarification/changes noted above are minor.

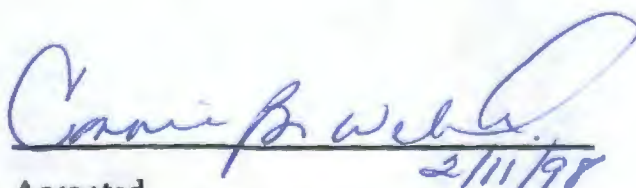
If I have accurately captured the agreement reached in our telephone conversation, I would appreciate your signing below and faxing this text back to me at 301 652 5408 authorizing immediate shipment of Virkon S using the November 17, 1997 label text.

Thanks for your assistance in resolving this matter expeditiously.

Respectfully submitted,



Jeff Jones, Agent  
Antec International Ltd.

  
2/11/98

Accepted  
Connie Welch, Chief  
Regulatory Management Branch II



## Antec International Ltd

Fa/la

21<sup>st</sup> February 1997

American Regional Office  
7635 Ashley Park Court  
Suite 503 F & G  
Orlando  
Florida 32835  
USA  
Tel 1 407 290-1127  
Fax 1 407 290-2755  
Internet <http://www.antecint.com>

Mr Robert Brennis  
Acting PM 32 Antimicrobial Division  
Office of Pesticide Programs (H7504C)  
US EPA  
401 M St SW  
Washington DC 20460-0001

Re: Additional Agent for Antec International Limited: Company Number 62432

Dear Mr Brennis

Dr Alan R Wagner is Antec's agent of record for pesticide registration purposes with EPA. He has worked with Antec for several years as we've submitted amendments for our VIRKON S product. Historically VIRKON S has been intended primarily for agricultural uses.

Recently we have begun the process of amending our label to add institutional uses. Jeff Jones of Delta Analytical Corporation has been advising us with respect to these amendments. From time to time, he needs to discuss issues with you and your colleagues on our behalf. For that reason, I would like to appoint him as "co-agent" with Dr Wagner. Dr Wagner will continue as our primary agent and all mail correspondence should continue to be directed to his address.

If you have any question, please contact me.

Sincerely

Francis Auchincloss

cc j jones/dr wagner/tra/ra

fa/la/epa delta co agent/02/21/97

**Antec International leads the fight against disease worldwide**

Directors: T.R. AUCHINCLOSS BSc C Chem PRSC FRCM FRCM (Chairman) T.R. AUCHINCLOSS BA FRCM MInst (Managing), R.F. AUCHINCLOSS J HAMPTON S.R. CRADOCK (Finance)  
Registered Office as above Registered No. 690279 England





**Antec**  
INTERNATIONAL  
LEADERS IN BIOSECURITY

3rd November 1997

Document Processing Desk (COADR)  
Office of Pesticide Programs - H7504C  
U S Environmental Protection Agency  
401 M Street SW  
Washington DC 20460-001

Dear Sir/Madam

**AUTHORISATION FOR REPRESENTATION/AGENT STATUS**

Pursuant to 40 CFR § 152.50(b)(3), we hereby designate the following company as an authorised agent to act in behalf of our company with respect to particular registration matters, regulated through the FIFRA (as amended), that may come before the Agency. The address of record for such matters will be:

EPA Company #62432  
Antec International Ltd  
c/o Farnam Companies, Inc  
301 West Osborn  
Phoenix AZ 85013

Contact: Dr Douglas H Ross

Phone#: 602/207-2108

This authorisation will remain valid until further notice is given by either our company or Farnam Companies, Inc.



Antec International Ltd

**Antec International Limited**

Witcham Road • Canton Industrial Estate • Sudbury • Suffolk • CO10 6XU • UK



Antec International

Tel: +44 (0) 1787 372 205 • Fax: +44 (0) 1787 372 246 • Web: <http://www.antec.co.uk> • Email: [Antec\\_International@compuserve.com](mailto:Antec_International@compuserve.com)



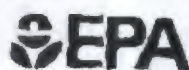
Thank you for expediting this request. If you have any questions please feel free to contact us

Yours faithfully

Ralph Auchincloss  
Chief Executive

cc Dr Doug Ross - Farnam  
1457400 Japa Farnam



Form Approved  
OMB No. 2000-0014  
Approval expires 2-28-96

U.S. ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF PESTICIDE PROGRAMS (TS-767)  
WASHINGTON, DC 20460

# NOTICE OF SUPPLEMENTAL REGISTRATION OF DISTRIBUTOR

(Please read instructions before completing)

## INSTRUCTIONS

After a registrant has obtained final registration for the basic product, the registrant may then supplementally register and distribute further product. One form must be submitted for each distributor brand and must be signed by the distributor involved. The form must state the basic registration number and the distributor company number.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting a Distributor Notification to the Agency.

Notification forms must be submitted by the basic registrant. They must have the concurrence and signature of both the registrant and the distributor.

When submitting several forms for the same basic product, submitting them together will facilitate processing.

NOTE: DO NOT submit distributor product labels.

## CONDITIONS

1. The distributor product must have the same composition as the basic registered product.
2. The distributor brand product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so no other changes are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic registered product, followed by a hyphen and the distributor's company number.
6. Distributor products must bear the name and address of the distributor qualified by such terms as "packed for . . ." "distributed by . . ." or "sold by . . ." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor brand products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

EPA REGISTRATION NO. OF PRODUCT

DISTRIBUTOR COMPANY NUMBER

62432-1

270

NAME AND ADDRESS OF BASIC REGISTRANT (print or type; include ZIP code)

ANTEC INTERNATIONAL, LTD.  
Windham Road,  
Chilton Industrial Estate  
Sudbury, Suffolk CO10 8XN  
England

NAME OF REGISTERED PRODUCT (basic product name accepted by EPA)

VIRKON S Broad Spectrum Disinfectant

DISTRIBUTOR PRODUCT NAME

VIRKON S Broad Spectrum Disinfectant

NAME AND ADDRESS OF DISTRIBUTOR (print or type; include ZIP code)

Livestock Products Division  
Farnam Companies, Inc.  
P.O. Box 34820  
Phoenix, AZ 85014

## DISTRIBUTOR

We intend to market under the Distributor Product Name and Number specified above, subject to the conditions specified on this form.

SIGNATURE AND TITLE OF DISTRIBUTOR

*Douglas H. Ross*  
Douglas H. Ross, Regulatory Specialist

DATE

9 FEB 98

## REGISTRANT

It is requested that the Registration Record of this jacket include the Distributor Product specified above, subject to the conditions specified on this form.

SIGNATURE AND TITLE OF REGISTRANT

*Alan R. Wagner D.V.M., M.S.*  
Alan R. Wagner, D.V.M., M.S., Agent for

DATE

10 October 1997

RECEIVED BY EPA REGISTRATION  
DIVISION ON THE DATE STAMPED  
BELOW

EPA Form 8670-5 (Rev. 4-83) Previous editions are obsolete.

Antec International, Ltd.

U.S. GOVERNMENT PRINTING OFFICE: 1984 - 431-389/0017

TOTAL 367.06





## FARNAM COMPANIES, INC.

301 West Osborn Road, Suite 2000  
Phoenix, Arizona 85013-3928  
Phone: (602) 285-1660 • fax: (602) 285-1803

Office of Corporate Development

Thursday, January 8, 1998

Document Processing Desk [NOTIF]  
Office of Pesticide Programs (7504C)  
US EPA  
Room 266A, Crystal Mall Building 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

Attention: Portia Jenkins (PM-34)

Subject: Virkon S Broad Spectrum Disinfectant  
EPA Reg. No. 62432-1  
Notification Per PR Notice 95-2  
Your Letter Dated December 2, 1997

Dear Ms. Jenkins:

I am writing to request quick reconsideration of the decision to reject the notification listed above. Because of public health concerns outlined below, it is in the Agency's interest to reconsider its initial judgment. I believe reconsidering this decision will take less than an hour of your time.

Of course, the Agency has the authority to reject a notification that it feels does not meet the *letter* of PR Notice 95-2 requirements. Likewise it has the authority to accept notifications that satisfy the *spirit* of the Notice. In this instance there are good public policy reasons for the Agency to accept the notification.

Whether the notification submitted meets the letter of PR Notice 95-2 governing notifications, it clearly meets the spirit. A literal and absolutely strict interpretation of 95-2 might require such revisions to be submitted as an amendment. A quick review of the label revisions, however, would indicate that they are strictly revisions of grammar and phrasing with no impact on hazard, risk or efficacy.

The proposed revisions were made solely with the intent of improving the readability of the instructions and to promote and ensure proper use of the product. No revisions negate or detract from required precautionary or other label statements; none trigger efficacy, human health or environmental concerns; none change the dosage, frequency, concentration, or method of application; no use patterns are added or deleted; and none of the statements are false or misleading since they rephrase the previously approved language.



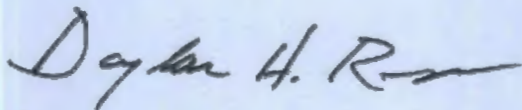
In a time when animal health issues are of increasing public concern, the Agency needs to ensure an adequate supply of safe and efficacious antimicrobial products. Virkon S was recently selected for testing at the USDA Foreign Animal Disease Laboratory at Plum Island, NY, as a single material to replace a variety of disinfectants, some unregistered by EPA. USDA recognized the wide range of activity Virkon S offers against disease causing pathogens that affect animal health, the low toxicity of the in-use solution, and the ease of use. In the current environment of public concern about animal health diseases and their impact on human health, it would be unfortunate for EPA to make a decision that could make the problem worse.

Farnam is the new U.S. distributor for Virkon S, and the supply of product available through the previous distributor is running short. Packaging incorporating the new language has been received, and the English manufacturer, Antec International Ltd., is waiting to fill these bags for shipment to the U.S.. Unless shipment can begin by January 15, 1998, there is a significant danger of supply shortages.

Looking back, whether these label revisions should have been subject to amendment or notification procedures is questionable. However, in view of the public health issues involved, I urge you to spend an hour to satisfy yourself that these revisions can be accepted as a notification. I respectfully ask that you conduct that short review over the next few days to assure that shipments can begin by January 15. If you haven't the authority to do so, please call me immediately so that I can contact Ms. Welch, and if necessary, Mr. Sanders to ask their assistance.

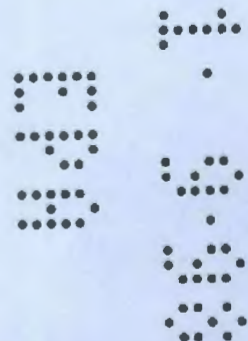
Thank you.

Sincerely,



Douglas H. Ross, Ph. D.  
New Product Development Manager  
& Regulatory Specialist

cc: M. Cortlund



Reviewer ID

L. Dobbins

Submission No.

5533908

Data Package No. \_\_\_\_\_

## CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 62432-1 PM 34 Action Code 33210 Descriptor (Amend/Resubmissions only) Label revision5 Intrastate Call-in ☐ (Y) Yes ☐ (N) No 15 Child-resistant Packaging ☐ (C) Certification ☐ (S) Service Person20 Registration Type: ☐ (1) Conditional ☐ (2) Unconditional ☐ (R) Non-residential Use Only ☐ (N) Not-Applicable25 Proposed Classification: 30 Final Classification:☐ (R) Restricted ☐ (R) Restricted ☐ (G) General ☐ (N) Not Classified35 Date on Application: 04 EPA Received Date: 40 Date Received by PM  
MO DAY YR MO DAY YR MO DAY YR  
1 1 18 97 1 1 20 97 1 1 24 9780 Method of Support:☐ (1) Cite-All ☐ (6) Owner Submission ☐ (4) Not Applicable ☐ (7) Total Submission ☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:

CH  
EF  
PL  
DEB  
NDEB  
TB  
EEB  
EFCB

DATE SENT	DUE DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE

115 FINAL Response ACTION Code 38120 Response DEC - 2 1997  
MO DAY YR75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☐ (N) No



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Dr. Douglas H. Ross  
Farnam Companies  
301 West Osborn  
Phoenix, AZ 85013

DEC - 2 1997

Subject: Virkon S Broad Spectrum Disinfectant  
EPA Registration Number 62432-1  
Notification Per PR-Notice 95-2

Dear Dr. Douglas H. Ross:

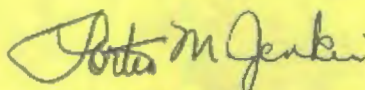
This will acknowledge receipt of your notification, for revised labeling, submitted under the provisions of FIFRA section 3 © 9. Based on a review of the submitted material, the following comments apply:

The application can not be processed as a notification and it is being returned without action. Per your application dated November 18, 1997, to revised the above reference product's label to remove redundant statements in bold italics and other label changes is considered unacceptable as a notification. Therefore, this application should be re-submitted as an amendment to this registration indicating new label revisions to your prime product name "Virkon S Broad Spectrum Disinfectant".

We are rejecting these labels "Virkon S Broad Spectrum Disinfectant" in which they do not qualified under PR Notice 95-2 as a notification and no further action will be taken until the agency receives your amendment for new labeling revisions under the product name Virkon S Broad Spectrum Disinfectant for review.

If you have any questions, please contact LaVerne Dobbins at (703) 308-6378.

Sincerely,



Portia M. Jenkins  
Acting Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510W)

CONCURRENCES

SYMBOL	7510W						
SURNAME	Jenkins						
DATE	12-2-97						



# NOTIFICATION

# EPA

United States Environmental Protection Agency  
Office of Pesticide Programs (H7505C)  
Washington, DC 20460  
Application for Pesticide:

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number  
**248162**

## Section I

1. Company/Product Number <b>62432-1</b>	2. EPA Product Manager <b>P. Jenkins (acting)</b>	Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>Virkon S Broad Spectrum Disinfectant</b>	PM# <b>34</b>	
5. Name and Address of Applicant (Include ZIP Code) <b>Antec International Ltd.</b> <b>c/o Farnam Companies, Inc.</b> <b>301 West Osborn</b> <b>Phoenix, AZ 85013</b>		<b>Expedited Review.</b> In accordance with FIFRA Section 3@ (3) (b)(i), my product is similar or identical in composition and labeling to:  <b>EPA Reg. No.</b> _____ <b>Product Name</b> _____

☐ Check if this is a new address

## Section II

<input type="checkbox"/> Amendment - Explain below <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - explain below.
---	---

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.) Notification of combination of labeling statements to remove redundancy, per PR Notice 95-2. This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the CSF of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

## Section III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)	If "Yes," Unit Package wgt.	No. per container
If "Yes," Unit Package wgt.		No. per container		If "Yes," Package wgt.	No. per container

**\*Certification must be submitted.**

3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) of Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
--	--------------------------------	---

6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	<input type="checkbox"/> Other (_____)
---	--

## Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name <b>Douglas H. Ross, Ph. D.</b>	Title <b>Agent for Antec International</b>	Telephone No. (Include Area Code) <b>302/207-2108</b>
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		
2. Signature 	3. Title <b>Agent for Antec International</b>	6. Date Application Received (Stamped) <div style="text-align: center;"> </div>
4. Typed Name <b>Douglas H. Ross, Ph. D.</b>	5. Date <b>NOV 18 1997</b>	





## FARNAM COMPANIES, INC.

301 West Osborn Road, Suite 2000  
Phoenix, Arizona 85013-3928  
Phone: (602) 285-1660 • fax: (602) 285-1803

Office of Corporate Development

Tuesday, November 18, 1997

Document Processing Desk [NOTIF]  
Office of Pesticide Programs/US EPA  
Room 266A, Crystal Mall Building 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

**Subject:** *VIRKON S Broad Spectrum Disinfectant*  
**EPA Reg. No.:** 62432-1  
**Regulatory Action:** NOTIFICATION of combination of labeling statements to remove redundancy, per PR Notice 95-2

Dear Ms. Jenkins:

Per PR Notice 95-2, [II. A. 10.], ANTEC International, Ltd., hereby notifies the Agency that they have revised the above referenced product's label to remove redundant statements. As documentation for this Notification, the following are enclosed:

1. Application for Pesticide Registration (Form 8570-1);
2. Revised Product Labeling (1 copy) with the changes shown in *bold italics*;
3. A copy of the EPA stamped, approved label for *VIRKON S Broad Spectrum Disinfectant*;
4. A copy of ANTEC's letter to the EPA, authorizing Farnam Companies, Inc., and myself, to act as their agent in registration matters.

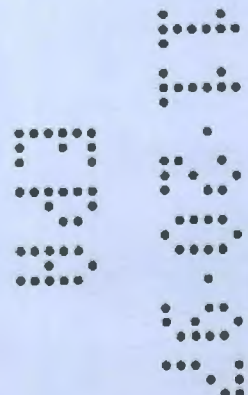
If you have any questions, please contact me at 602/207-2108. Thank you.

Sincerely,

Douglas H. Ross, Ph. D.

New Product Development Manager & Regulatory Specialist

xc: R. Blomquist  
M. Cortlund  
R. Auchincloss - ANTEC



**VIRKON-S<sup>®</sup>**  
**BROAD SPECTRUM DISINFECTANT**

**For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities**

**ACTIVE INGREDIENTS:**

Potassium peroxymonosulfate.....	20.4%
Sodium Chloride.....	1.5%
INERT INGREDIENTS.....	<u>78.1%</u>
TOTAL.....	100.0%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

**See Back [Side] Panel[s] for Additional Precautions**

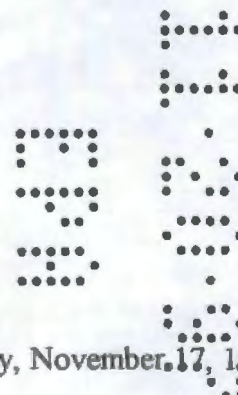
\_\_\_ lbs. (\_\_\_) Net Weight

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

**ANTEC INTERNATIONAL LTD.**  
Windham Road, Chilton Industrial Estates  
Sudbury Suffolk CO10 6XD, England  
Tel: (1787) 77305 Telx: 987495 Fax: (1787) 310846

VIRKON S is a registered trademark of and manufactured by Antec International Limited  
US Patent No. 4822512



Monday, November 17, 1997



## EQUINE BACTERIA

Clostridial diarrhea  
Fistulous Withers (Poll Evil)  
Taylorella Equigenitalis  
Streptococcus equi (Strangles)  
Pseudomonas mallei  
(Gianders)  
Bordetella bronchiseptica

## EQUINE VIRUSES

African Horse Sickness  
African Viral Arteritis (Pink Eye)  
Coital Exanthema  
Myeloencephalopathy  
Rhinopneumonitis  
Equine Infectious Anemia  
(Swamp Fever)  
Equine papillomatosis  
Equine Contagious Abortion  
Adenovirus Pneumonia  
Equine Influenza (The Cough)

## EQUINE FUNGI

Dermatophytosis (Ringworm)  
Dermatophylosis (Mud Fever)  
Fusarium moniliforme

## BOVINE BACTERIA

Moraxella bovis  
Mycobacterium bovis  
Haemophilus somnus

## BOVINE VIRUSES

Calf rotavirus  
Infective Bovine  
Rhinotracheitis  
Bovine Adenovirus Type 4  
Pseudorabies

Foot & Mouth Disease

## BOVINE FUNGI

Fusarium moniliforme

## EFFECTIVE AGAINST:

### BACTERIA

Streptococcus pyogenes  
Campylobacter pyloridis  
Klebsiella pneumoniae  
Escherichia coli  
Salmonella typhimurium  
Salmonella choleraesuis  
Pseudomonas aeruginosa  
Staphylococcus aureus  
Staphylococcus epidermidis  
Mycoplasma gallisepticum  
Clostridium perfringens  
Bordetella avium

### VIRUSES

Newcastle Disease  
Infectious Bronchitis  
Infectious Bursal Disease  
Avian Laryngotracheitis  
Avian Influenza  
Marek's Disease  
Egg Drop Syndrome  
Turkey Herpes Virus  
Duck Herpes Virus  
Duck Viral Enteritis

### FUNGI

Aspergillus flavus  
Aspergillus fumigatus  
Candida albicans

## SWINE BACTERIA

Bordetella bronchiseptica  
Pasteurella multocida  
Actinobacillus  
pleuropneumonia  
Treponema hyodysenteria  
Clostridium perfringens

## SWINE VIRUSES

Hog Cholera  
Swine Influenza  
Porcine parvovirus  
Rotaviral diarrhea  
Vesicular stomatitis  
Pseudorabies  
Porcine Reproductive and  
Respiratory Syndrome (PRRS)  
African Swine Fever  
Foot and Mouth Disease

## SWINE FUNGI

Fusarium moniliforme

## COMPANION ANIMALS

### BACTERIA

Streptococcus aureus  
Streptococcus pyogenes  
Klebsiella pneumoniae  
Pseudomonas aeruginosa

### VIRUSES

Canine Parvovirus  
Distemper  
Leptospira canicola  
Feline parvovirus  
Feline herpes  
Feline calicivirus

### FUNGI

Microsporum canis



**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
DANGER**

Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive statement refers to powder only not in use solution.

**FIRST AID**

**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention if irritation persists.

**IF INHALED:** If symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

**IF SWALLOWED:** Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

**NOTICE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

**BROAD SPECTRUM DISINFECTANT**

**VIRKON-S** is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material. ***VIRKON-S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.***

**DIRECTIONS FOR USE**

Federal law prohibits use of this product in a manner inconsistent with its labeling

This powder formula is easily diluted for use in manual or machine operations.

***VIRKON-S DILUTION CHART***

*Fill container with desired amount of water and add VIRKON-S powder to achieve recommended solution concentration.*

<i>Quantity of Water</i>	<i>Amount of Powder for 1% Solution</i>	<i>Amount of Powder for 2% Solution</i>
<i>1 Quart</i>	<i>0.3 ounces</i>	<i>0.7 ounces</i>
<i>1 Gallon</i>	<i>1.3 ounces</i>	<i>2.7 ounces</i>
<i>10 Gallons</i>	<i>13.4 ounces</i>	<i>26.7 ounces</i>
<i>50 Gallons</i>	<i>66.8 ounces</i>	<i>133.5 ounces</i>

*1.3 oz. measuring scoop provided.*

Monday, November 17, 1997



*Add [1.3 oz. (1 scoop) of VIRKON-S] [the contents of one VIRKON-S packet] to one gallon of warm water. Solutions are stable for 7 days. Do not soak metal objects for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.*

## POULTRY [AND RATITE PRODUCTION]

**CONTROLS:** Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*. Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium* and *Mycoplasma gallisepticum*.

**HATCHERIES:** VIRKON-S at 1% solution *can be used* for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). VIRKON-S at 1-2% solution is recommended for use in fogging (wet misting) operations as a *supplemental measure*, either *before or after* regular cleaning and *disinfecting* procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

**BROILER/BREEDER HOUSES:** *Remove chickens [birds], feed, and water troughs, then remove manure and litter. Spray floors and walls with VIRKON-S at 1% solution.* Thoroughly wash waterers and feeders with a 1% solution of VIRKON-S (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). *After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.*

**FOR AIR SANITIZING:** Use VIRKON-S at 1-2% solution, *and fog until* surfaces are moist. Allow at least 2 hours before entering *treated area*. *Rinse foggers and sprayers with water following use.*

**PROCESSING PLANTS:** *Spray VIRKON-S at 1% solution to disinfect and clean walls, ceilings and floors.*

## SWINE [PRODUCTION]

**CONTROLS:** Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine Fever and Foot and Mouth Disease. Bacteria of *Pleuropneumonia*, *Treponema hyodysenteriae*, and *Clostridium perfringens*. Fungi: *Fusarium moniliforme*.



**VIRKON-S at 1% solution** is recommended for *cleaning and disinfecting* farrowing units, nurseries, finisher houses and processing plants (use a 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus.)

**VIRKON-S at 1-2% solution** is recommended for use in fogging (wet misting) operations or as a *supplemental measure* either *before* or *after* regular cleaning and *disinfecting* procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. *Rinse foggers and sprayers with water following use.*

## EQUINE [PRODUCTION]

### BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

#### CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis. Bacterial: Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders). Fungi: Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), and Fusarium moniliforme.

**APPLICATIONS:** For cleaning and *disinfecting* all surfaces, equipment, utensils and instruments in Veterinary practices [, kennels, stables, catteries, etc].

#### USES:

**Topical Use On Animal:** Shampoo infected area with *a 1% solution of VIRKON-S* using a clean sponge. Rinse with clean water. Apply three times a day. Repeat as necessary.

**Stables, [Horse Boxes, ][Box ]Stalls, Tack ,[Equipment,] and Feed Rooms:** Thoroughly *clean and dry* [dry clean] *surfaces*, then wash the area manually or with pressure washer with a 1% VIRKON-S solution. Rinse with clean water.

**Blankets, [Saddle Pads] [and] Rugs:** Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

**Aerial Spraying to control airborne diseases:** *Use a hand [or knapsack] sprayer with fine setting*, or an *automatic* spraying system. Spray *a 1% VIRKON-S solution* for 2-3 minutes twice daily [, first thing in the morning and last thing at night]. *Rinse sprayers with water after use.*

## BOVINE [PRODUCTION]

**CONTROLS:** Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies; Bacteria of Maraxella bovis, Haemophilus somnus and Mycobacterium bovis; Fungi of Fusarium moniliforme.



A 1% solution of VIRKON-S is recommended *to clean and disinfect* areas associated with bovine *housing* [stabling], hospital [quarantine] pens and feedlot facilities.

### COMPANION ANIMALS

CONTROLS: Viruses Canine Parvovirus, Distemper, Leptospira canicola, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa; Fungi of Microsporum canis.

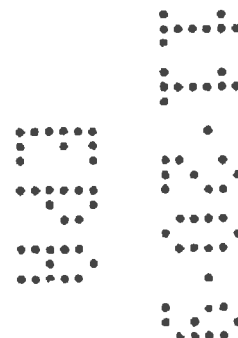
[APPLICATIONS:] A 1% solution of VIRKON-S is recommended as a "one step" cleaning and *disinfecting* procedure for all surfaces, equipment, instruments, utensils and *cages* [caging systems] within [associated with] [Veterinary Medical Hospitals,] [infections disease wards,] [quarantine areas,] [Humane Society facilities,] [laboratory animal quarters,] grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in VIRKON-S for long periods - 10 minutes is maximum contact time.

### STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

DISPOSAL: Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals



Monday, November 17, 1997



3rd November 1997

Document Processing Desk (COADR)  
Office of Pesticide Programs - H7504C  
U S Environmental Protection Agency  
401 M Street SW  
Washington DC 20460-001

Dear Sir/Madam

#### AUTHORISATION FOR REPRESENTATION/AGENT STATUS

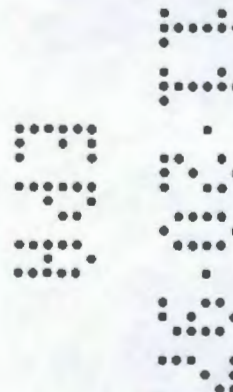
Pursuant to 40 CFR § 152.50(b)(3), we hereby designate the following company as an authorised agent to act in behalf of our company with respect to particular registration matters, regulated through the FIFRA (as amended), that may come before the Agency. The address of record for such matters will be:

EPA Company #62432  
Antec International Ltd  
c/o Farnam Companies, Inc  
301 West Osborn  
Phoenix AZ 85013

Contact: Dr Douglas H Ross

Phone#: 602/207-2108

This authorisation will remain valid until further notice is given by either our company or Farnam Companies, Inc.



INDEPENDENT PUBLICATION

Antec International Limited

Wingham Road • Chilton Industrial Estate • Sudbury • Suffolk • CO10 6XD • UK

Tel: +44 (0) 1787 377 305 • Fax: +44 (0) 1787 310 846 • Web: <http://www.antechnl.com> • E-mail: [antec\\_international@cc.mpsuerve.com](mailto:antec_international@cc.mpsuerve.com)



724 No 231216





Thank you for expediting this request. If you have any questions, please feel free to contact us.

Yours faithfully

Ralph Auchincloss  
Chief Executive

cc Dr Doug Ross - Farnam  
ra97/kwr/epa.farnam

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SEP 2

Antec International LTD.  
c/o Dr Alan Wagner, DVM, MS  
2821 River Park Dr  
Columbus, OH 43220

Dear Dr. Wagner:

Subject: Additional labeling claims  
Virkon S  
EPA Registration No. 62432-1  
Your resubmission of March 11, 1997

We have completed a preliminary review of your application and have determined that the application cannot be processed further for the following reasons:

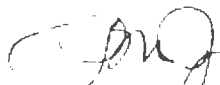
1. The following studies are not **Guideline Studies**:
  - a) Investigation to Test the Effect of Prolonged Spraying of Livestock with VirKon-S MRID 442343-01
  - b) Trials in Poultry With A Sprayed Disinfectant-Virkon-S MRID 442343-2
2. The following studies are **Guideline Studies** but they are not require to support the additional claims.
  - a) The Eye Irritation Study in the Rabbit MRID 442420-01
  - b) Skin Irritation Corrosivity Study in the Rabbit MRID 4424200-2
3. The additional animal claims you have added to your labeling must be approved by FDA.
4. Before the Agency can accept this product for drinking water systems the product must be Certified by the National Sanitation Foundation International (NSF International). You must contact the following person:

Mr. Dave Purkiss, General Manager  
NSF International  
P.O. Box 130140  
Ann Arbor, Michigan 48113-0140  
Phone: 313-769-0109



In the future please highlight all label additions and changes. If you have any questions concerning this letter please contact Portia Jenkins at (703) 308-6230.

Sincerely yours,



Portia M. Jenkins  
Acting Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510W)

**DR. ALAN R. WAGNER**  
Regulatory Affairs and Technical Services

Private Consultant  
Clinical Investigations

2821 River Park Drive  
Columbus, Ohio 43220

Ph: 614/459-5965  
Fax: 614/459-9875

March 29, 1996

Ms. Ruth G. Douglas (PM32)  
Antimicrobial Program Branch  
Registration Division (H7505C)  
U.S. Environmental Protection Agency  
Room 278, Crystal Mall II  
1921 Jefferson Davis Highway  
Arlington, VA 22202

RE: VIRKON S  
EPA Registration Number: 62432-1  
Amendment Dated August 8, 1995  
And Your Letter of Response Dated  
March 7, 1996

Dear Ms. Douglas:

Thank you for your letter of March 7, 1996 in response to our amendment of revised master-labeling for **VIRKON S**. This label amendment superceded the ones dated April 11th and June 20th, 1995, as we agreed during our telephone conversation. I most certainly appreciated your assistance in this request.

I have reviewed and discussed with my client, Antec International, Ltd., your letter of March 7th, 1996 regarding your comments and unacceptability of the proposed labeling as submitted. Your letter proved most helpful in clarifying the issues in question as identified on the submitted labeling. We too had concerns that diseases rather than infectious organisms were present on previously approved labels.

Regarding our label claims for animal pathogens, these are zoonoses organisms, as you know, infecting both humans and animals and by default the reference refers to animal use only.

As a point of inquiry regarding the preparation of the resubmittance of an Application For Amendment in accordance with your letter of March 7, 1996, we would appreciate your review and guidance as to our proposals for acceptance and inclusion into our resubmitted Application For Amendment responding to the following points covered in your letter.

**Comment # 1:** "Delete *Campylobacter coli* and *Campylobacter jejuni*. These are also human pathogens. Data required." ----- We have enclosed data as requested. See Ref. No. 23.

**Comment # 2:** "Delete *Leptospirosis*." ----- We will delete on resubmission

**Comment # 3:** "Delete *Salmonella enteritidis*. This is a human pathogen. Data Required." ----- We have enclosed data as requested. See Ref. No's. 28 & 70.



**Comment # 4:** "Delete Parainfluenza. This is a human pathogen. Data required." ----- We have enclosed data as requested. ----- See Ref. No. 71.

**Comment # 5:** "Delete Leukoencephalomalacia and Moldy Corn Poisoning. These are diseases." ----- These disease entities will be deleted from label resubmission since the etiological agent is *Fusarium moniliforme*. We have enclosed data for this organism. See Ref. No. 73.

**Comment # 6:** "Delete *Listeria monocytogenes*. This is a human pathogen. Data required." ----- We have enclosed data in reference to this organism being identified as a zoonotic disease. See Ref. No. 70.

**Comment # 7:** "Delete *Erysipelothrix rhusiopathiae*. This is a human pathogen. Data required." ----- We have enclosed data in reference to this organism being identified as a zoonotic disease. See Ref. No. 70.

**Comment # 8:** "Delete Bovine viral diarrhea. This is a disease." ----- This entity should be identified as BVD Pestivirus. We have enclosed data. See Ref. No. 71.

**Comment # 9:** "Delete Atrophic rhinitis, Colibacillosis, Enteritis, Mastitis, Necrotic Enteritis and Salmonellosis. These are diseases." ----- Atrophic rhinitis would be replaced by *Bordetella bronchiseptica* and *Pasteurella multocida*, both associated with this disease entity. We have enclosed data relating to this entity. See Ref. No's. 70 & 125.

Colibacillosis will be replaced with *E. coli*. Data is enclosed. See Ref. No. 109.

Enteritis, Mastitis, Necrotic Enteritis and Salmonellosis will be deleted from the resubmitted label.

**Comment # 10:** "Delete Transmissible Gastroenteritis. This is a disease." ----- This entity will be replaced by TGE coronavirus. We have enclosed data. See Ref. No. 71.

**Comment # 11:** "Delete Parainfluenza, Infectious hepatitis and Oral papillomatosis. These are diseases." ----- We would modify this entity as Parainfluenza virus, being a zoonotic organism to which several livestock species are susceptible.

Infectious hepatitis would be deleted and replaced by Infectious canine hepatitis (Adenovirus). We have enclosed data. See Ref. No. 49.

Oral papillomatosis would be replaced by Bovine papilloma virus. We have enclosed data for this entity. See No's. 2 & 110.

**Comment # 12:** "Delete Coronavirus. This is both a human and animal pathogen. Data are required." ----- This pathogen will be replaced on the label by TGE coronavirus and Infectious bronchitis virus. We have enclosed data as requested. See Ref. No's. 71 & 131 respectively.

**Comment #13:** "Delete Rabies. This is a disease." ----- This entity will be deleted on resubmission.

**Comment # 14 - 15:** All references to use of VIRKON S in cleaning, sanitizing and disinfecting institutional and food processing and service facilities and references for use of product for the protection of hotel guests and ship passengers will be deleted in the preparation of the resubmittance of our Application For Amendment.

We are anxious to respond to your letter of March 7, 1996 and to amend our resubmission of VIRKON S Master Labeling in accordance with your comments and would appreciate your counsel and advice concerning our tentative responses to the comments defined in your letter

Again, I want to thank you for the assistance and courtesy extended to me regarding our Regulatory Affairs concerns. I also hope, Ms. Douglas, that you have fully recovered from your illness and that I may have the opportunity to visit you in the near future. I would be most grateful for your advice and comments in reference to this submission.

Sincerely,

*Alan R. Wagner*

Alan R. Wagner, DVM, MS  
Agent for Antec International Ltd.

ARW/mw

VIA CERTIFIED MAIL

cc: Francis Auchincloss  
Antec International, Ltd.

